Development and validation of a patient-based outcome measure for endodontic treatment

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DEVELOPMENT AND VALIDATION OF A PATIENT-BASED OUTCOME MEASURE FOR ENDODONTIC TREATMENT

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ABSTRACT

Background: in 1970's the seminal work of Cohen and Jago initiated an interest in the measurement of health related quality of life measures in dentistry. Clinical measures to assess oral health from the dentist's perspective do not necessarily measure well-being. The patient reported outcome measures are an important tool to measure and improve the quality of care.

Aim: The aim of the project was to create and validate a brief instrument for measuring patient-based oral health outcomes associated with endodontic care.

Method: Based on the literature review of the currently used core oral health outcome measures, items from established instruments were selected to generate pool of items for the new measure. All subjects attending primary dental care at a local dental teaching hospital specifically for endodontic treatment provided by undergraduates self-completed this outcome measure prior to, immediately following care and at one month follow-up visit. Using multicollinearity, factor analysis, regression modelling and an expert based approach items were identified for a brief instrument. The newly developed brief instrument was tested for its reliability, validity and responsiveness on patients attending for endodontic treatment in the same clinical setting using the self-completed questionnaire at the baseline and after completion of the treatment.

Results: 46 Items from OHIP-49 (Oral Health Impact Profile) and 12 items from GOHAI (General Oral Health Assessment Index) were used as the basis for development of an endodontic outcome measure. Multicollinearity, factor analysis and regression analysis of the long-form of the instrument (58 items) identified 15 significant items associated with improved oral health. One item was added to the questionnaire by an expert based approach to encompass all the seven domains (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap). The newly developed measure was strongly associated with self-rating of oral health ($P<0.05$). In terms of sensitivity, there was an observed gradient in the mean change of overall scores before and after treatment ($P<0.05$) in each of the 16 items. The measure demonstrated reliability (Cronbach's alpha 0.85); changes in the measure were correlated at the individual item level, and were statistically significant ($P<0.05$). In paired sample t-test the values of each individual item in the questionnaire led to a significant difference between pre- and post-treatment scores ($P<0.05$). There was an observed gradient in the mean change of overall scores before and after treatment ($P<0.05$) supporting the construct validity and responsiveness of the measure.

Conclusions: The new 16-item instrument demonstrated satisfactory face, construct and criterion validity as well as good internal reliability and test and retest reliability for each item across all seven domains. The findings suggest that the measure is sensitive and responsive to the effects of the endodontic treatment in a dental hospital primary care setting.

DEDICATION

To my parents, who inspired me and supported me every step of the way.

To my lovely wife for her unwavering support during my years of formal (and informal) education; I thank you for your love, patience, sacrifice, and understanding in my pursuit for something better. I love you more than words can describe.

To my wonderful son; the time not spent with you during my professional training and research will ultimately allow me to spend more time with you in the future; I do this all for you.

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CHAPTER 1 INTRODUCTION

1.1 INTRODUCTION

During the second half of the twentieth century the world start shifting from materialistic values that focus on economic growth and security to post materialistic values that focus on self-actualization and self-determination as reported by Inglehart (2002). For the materialistic value orientated patients dental health can be just healthy teeth and gums but for post materialistic orientated patients it is far beyond healthy gums and teeth and may include aesthetic concerns, impacts of facial appearance on self-esteem and interaction with the society.

The World Health Organization (1948) definition of health introduced a paradigm shift in the definition of health and in the field of dentistry this new perspective of health has suggested that the ultimate goal of dental care should not be merely just absence of disease in the oral cavity but that the patient's mental and social well-being should also be taken into account. In 1976, Cohen and Jago (1976) called for socio-dental indicators of oral health that has led to a development of numerous socio-dental indicators (Corson et al., 1999) that measure both the social and societal impacts of the disease. However, still the predominant measurement focus in dentistry remains disease (Reisine et al., 1995) and there are still many more research findings related to function and the ageing population than in any other areas as reported by Gift (1997).

As the concept of oral health quality of life brings a new perspective to clinical care and research. As it shifts the focus of clinicians and researchers from the oral cavity alone to the patient as a whole, so this concept can make a valuable contribution to the clinical practice of dentistry, dental research and dental education. As reported by Corson et al. (1999) the QoL measurement in dentistry is here to stay as it is central to a proper evaluation of the impact of dental care. Dijkers et al. (1999) have explained that in the current health climate there is desired a need for patient based outcome measures as traditional clinical measures are of little interest for patients; he named the term "real life".

Slade and Spencer (1994) have discussed that in determining health priorities, health outcome measures can play a crucial role, while Slevin et al. (1998) have pointed out that a patient's assessment of their health related quality of life (HRQoL) is often different to the opinion of health care professionals.

Endodontic treatment is one of the complex treatments encountered by the general dental practitioner's in general dental practice, the new information is still emerging, evidence based dentistry and large-scale survey of post-endodontic patients have reported that endodontic treatment not only saves the tooth, more than 97 percent of surveyed patients reported satisfaction with their endodontic treatment and also reported significantly improvement in their quality of life (Dugass et al., 2002). Outcomes of endodontic treatment are usually assessed by strict criteria including complete healing of periapical disease and clinical function without signs or symptoms. A tooth that has incomplete radiographic healing at the time of re-evaluation would not be considered a success by this definition, even if it was asymptomatic and fully functional (Kvist 2001). Evaluating patients' perceptions and the psychosocial effect on their quality of life are likely critical to patients (Torabinejad et al., 2007) and therefore should be taken into consideration by the clinician in evaluating outcome of any dental treatment and endodontic is one of the complex dental treatments.

There is a need to investigate the association between dental care and HRQoL as patients under care need to know that dental treatment does something that in the patient's perception improves their quality of life. This thesis is an attempt to look at how endodontic treatment improves the quality of life of patient's. It is conducted at King's College London Dental Institute which provides a primary care setting for students to gain experience in clinical care prior to qualification.

It is clear from a review of the literature and evidence based practice dentistry that appropriate treatment must be based with the patient's best interests and long-term quality of life at heart.

The prominence of OHRQOL in public policy seems to be a relatively recent phenomenon as reported by the US Surgeon General (2000). A comprehensive literature search shows that since the early twentieth century dental researchers have more focused on detailed epidemiological assessments of oral health using a predominantly clinical

focus on disease and tissue destruction, thus Dean and colleagues (1942) developed DMF index for dental caries and similar comparable clinical indices that measure gingival inflammation, dental trauma, periodontal tissue destruction, orthodontic irregularities, and temporomandibular disorders followed. However, because of the limitations of these measures only one can only tell about the state of the tissues comprising the oral cavity but nothing about the function and well-being of the person.

As reported by Inglehart and Bargramian (2002) in the early twentieth century researchers regarded most oral diseases as a personal experience that caused a minor inconvenience to a subject and had nothing that could be related to general health status. Gerson (1972) reported that oral disease was not viewed as an illness because the oral conditions were rarely associated with a classic "sick role". Dunnell and Cartwright (1972) found trouble with teeth was a considered "trivial" problem and was not accepted as ill health. Davis (1976) suggested, by analysing data from the first international Collaborative Study of Dental Manpower Systems, that aside from pain or a rare life threatening neoplasm , oral disease effects on social roles is only associated with perception of self-esteem or with ethics only.

The behavioural/psychosocial measures, as their name indicates, are subjective measures which address perceptions, feelings and behaviours and assess health, well-being and quality of life. They began to develop in medicine shortly after the Second World War. Their development resulted from an important philosophical change in perception of health beginning in 1948 with the World Health Organization definition of health as a "complete state of physical, mental and social well-being and not just the absence of illness" (WHO, 1948). Increasing expenditure on health services also was a motive to look for evidence whether the health of the people was improving but was insensitive to health statistics such as mortality and clinical markers of morbidity. This lead to a beginning of a shift from what we call a uni-dimensional biomedical model with its emphasis on biology and disease to a multidimensional bio psychosocial model which incorporates concerns with functioning, well-being and quality of life.

As the demand grew for measures of health status, researchers have developed a number of standard questionnaires that have been applied in clinical settings or large population surveys. There are large numbers of generic and disease specific instruments that are

applied in randomized controlled clinical trials, evaluation of health care delivery systems and technology assessments in health care.

According to the Department of Health (1994) “Oral health is a standard of health of the oral and related tissues which enables an individual to eat, speak and socialize without active disease , discomfort or embarrassment and which contributes to general well-being”. However, as Locker (1997) reported clinical indices like the DMF index or CPTIN can measure existing or past dental disease and may in some situations be used to provide an indication for treatment need but they fail to give any form of the indication of the functioning of the individual or the social and the psychological impact of the disease. The oral related quality of life term has emerged rapidly in the last 10 to 15 years but if we go a further deep in history oral health was first considered in terms of quality of life during the second world war as Hatch et al. (1998) reported that the presence of six opposing teeth was used to assess suitability for service so those teeth were an indicator of oral functioning and well-being.

Cohen and Jago (1976) were the initiators in oral health who in 1976 were the first to advocate the development of a ‘socio-dental’ indicator to capture non-clinical aspects of oral disease. They argued that socio-dental indicators were necessary to broaden the narrow focus that had emerged in oral epidemiology which just emphasized only the clinical parameters of disease but failed to capture the full aspects of oral disorders within the population.

In terms of the development of oral health related quality of life measures, the most important development was Lockers (1988) conceptual model based on an adaptation of the World Health Organizations (1980) classification of Impairment, Disability and Handicap. The Locker model (1998) provided a more comprehensive approach to capture the multidimensional nature of oral health; it encompassed not only the biophysical issues, but also the psychological and social effect.

The Oral Health Impact Profile (OHIP) was based on the Lockers model (1998) and is now the most widely used instrument in oral health it has been used to assess the impact on quality of life of various oral conditions in Adult Dental Health Survey 1998 and 2009.

Since the development of socio dental indicators there has been a great deal of research on the development of questionnaire instruments to measure oral health related quality of life (Gift, 1996). Focusing solely on clinical indicators may not directly reflect the problems people experience as a result of their dentition.

In this thesis, oral health, dental health, oral health related quality of life measures and oral health outcome measures will be used as synonymous concepts.

1.2 Overview of the thesis

Chapter 2 provides an overview of the literature including the historical background of quality of life measures, models of health, generic health measures and oral health measures. Chapter 3 contains the aim and objectives of the study. Chapter 4 contains the methodology, methods and materials. Chapters 5-7 display the results of the study and lead to the discussion is in Chapter 8. The overall conclusions and a list of recommendations are presented in Chapter 9.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

This chapter sets the scene for the study by reviewing and critically appraising the relevant literature available on the existing health outcome measures both generic and oral health specific measures. It starts by describing the development of the biomedical and bio-psychosocial models of health. The chapter then examines the concept of positive health. The emergence of medical outcome movements and patient centered outcome movement along with current development towards a patient-centered approach in the NHS in general and dental health will also be discussed in this chapter. The rising importance of the concepts of health related quality of life (HRQoL) and oral health related quality of life (OHRQoL) has also been addressed in this chapter; there is a brief overview of endodontic treatment and quality of life. Finally a brief overview of the generic health outcome measures and oral health specific measures has been outlined.

2.2 THE BIOMEDICAL AND HOLISTIC HEALTH MODELS

Traditionally, health has evolved from a uni-dimensional model, where health is perceived as the absence of disease, the absence of pathology, to a multidimensional model which incorporates "complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (WHO, 1948). It has encouraged a shift of focus from the narrow and negative disease-based definition, towards a more positive concept of health. It distinguished wellness from lack of disability, disease and illness. In its definition the World Health Organization (WHO) acknowledges that an individual who is technically "cured" of disease may not be necessarily be "well" and went on to indicate three dimensions of well-being. It has encouraged health service researchers to look beyond clinical indicators of disease, and encouraged a shift of focus away from the narrow and negative disease-based definition, towards a more positive concept of health.

The traditional biomedical model is based on a belief that ill health is an objective and measurable state. This model has been characterized by HannuVuori (1980) as diseases are specific entities constituting specific problems and needing specific solutions as well as they are basically biological problems dealt with by medical means. The basic concept underlying the biomedical model is one of the hierarchy and subordination of people to a medical system and its personnel (HannuVuori, 1980). This focus created a mechanical approach to medicine; it shared the Newtonian tenet of mechanism that nature worked according to mechanical laws. This led to the emphasis in medicine on a structural theory of disease (that is, the disease has a place in the body-either in an organ or later cells) as argued by Engel (1989). Dubos (1960) described the medical model, in which the role of the physician was to treat disease and restore health by correcting any imperfections caused by accidents of birth or life with little consideration of the views or perceptions of the patients. The drawback of this model as described by researchers is that it shared Descartes dualism and separated the mind and body. Like the emerging science it was reductionist (Capra, 1986). The result was a paradigm of disease that was purely biological (Kriel, 1987). It is this paradigm that has been labelled biomedicine by Engel (1989). This paradigm has been at the heart of medicine for the last 100 years and resulted in successes of scientific medicine, it has laid the basis for the medicine's claim to be a science and not simply a clinical art (Coulter et al., 1994).

The accusations against the biomedical paradigm are that its reductionism, dualism, and biological determinism lead to neglect of the individual, the patient, in favour of its focus on the aetiology of disease (Mc Whitney, 1983). Kriel (1987) argued that it is unable to deal with the important health issues of the day, the lifestyle diseases. The three anomalies as isolated by Mc Whitney (1983) which cannot be handled by this model are: firstly, an increasing amount of illness dealt in clinics cannot be classified by its taxonomy of disease (the so called functional as opposed to structural diseases). Secondly, it fails to account for the social distribution of illnesses and lastly it is unable to give an explanation of placebo effects, possibly because it is unable to distinguish treatment from healing. This model has been widely criticized by society and Gordon (1980) has argued that the challenge to biomedicine has resulted in an articulate social critique of medicine and its theoretical base.

Cassel (1986) discussed that this model has had a profound effect on how doctors behave and on the relations with patients and that this paradigm is at the centre of the crisis in contemporary medicine.

If we summarize the critiques against this model, an ideology of scientism, the biology of illness and disease, the reduction of illness to specific causes or to simply the mechanisms of disease, the separation of mind and the body , the elevation of pathological anatomy as the basis for diagnosis and intervention, and lastly but the most important the loss of the traditional perspective of the whole person are the notions that have been established by researchers (Capra, 1986; Cassel, 1986; Berliner and Salmon, 1980; Armstrong, 1986).

The critics of the medical model have pointed to its limitations. They have discussed that the eradication of the disease if it is possible, will not necessarily achieve health, and it fails to address health needs but rather can be a cause for monopolisation of health care, iatrogenesis (clinical and cultural) and can lead to increased expenditure on health (Illich, 1977). Cuyler (1983) has pointed to its difficulty in adapting to emotional and psychiatric disorders. It also deemphasizes preventive medicine and ignores the social cause of disease and social customs in defining disease (Cuyler, 1983). Williams (1993) has argued a problem with this model is that one can be ill without having a disease, perceiving symptoms without pathology, or one can have a disease without being ill, or having a disease in a pre symptomatic stage. The advocates of the medical model have

attempted to conceptualize well-being as a departure from objective measures into subjective and ephemeral indicators but Greer (1986) has criticized it by arguing that this is misleading, because biomedical criteria are by no means clear themselves. However, Wood (1986) has discussed that the medical model as a paradigm has been highly productive in the advancement of medical science and health, and the spectacular advances in medical research in our lifetime are due to the success of this approach.

The most radical change within medicine was brought about by the proposed holistic health care movement within medicine brought by the American Holistic Medical Association founded in 1978. This movement proposed that medical practitioners would be holistic (non-reductionist) and focus on the total patient; naturalistic; humanistic; therapeutically conservative; developing a partnership relation between doctor and patient; caring and practicing in an environment that reinforces the dignity and power of the patient (Gordon 1980). This holistic paradigm replaces the traditional biomedical paradigm in way as suggested by Gordon (1980) that care would address the physical, mental and spiritual aspects of the patients; it would emphasize personalized individual care; care would include an understanding and treatment of people in the context of their culture, their family and their community. He proposed that this model should view health as a positive state and not simply absence of disease; care should emphasize the promotion of health and prevention of disease. This model views illness as an opportunity for discovery of the patient and the doctor; appreciates the quality of life in each of its stages; focuses on the therapeutic value of the setting in which health care occurs and tries to understand and change social and economic conditions that disseminate ill health. Norman Cousins (1979) writing outside of medicine also gave a boost to this approach "The basic strength of the holistic health movement is in the concept of the human body and mind as a fully unified biological system capable under most circumstances of warding off disease or overcoming it. According to this philosophy, the primary function of the physician is to engage to the fullest the ability of the body to right itself".

Different models have been proposed which are based on a new epistemological base for medicine. The most well-known model is known as "bio-psychosocial model" proposed by Engel's (1989). This is the model that takes into account the patient, the social context and the role of the physician and the health care system. This model proposes that primacy is not given to the biological factors but the physician must weigh the relevance

of biological, social or psychological factors. Broyd (1990) has argued that this model returns medicine to an appreciation of the patient and for illness to be understood within the full context of the patient's life. He also suggests that there are some data to support the claim that this approach to positive health has positive health and social outcomes. Cluff (1987) has also argued that the biomedical model cannot reveal current health problems and must be supplemented with a social perspective.

Bowling (1997) stated that illness refers to a patient's subjective experience of ill health and is indicated by reported symptoms and subjective accounts of pain, distress and discomfort and so on. It is an important distinction that a person might feel ill without medical science being able to detect disease. Parson (1951) has argued that the illness is a social phenomenon rather than a physical entity or property of individuals. Annandale (1998) stated that disease (the biophysical state) and illness (the social state) are distinct entities and "illness became the providence of sociology".

The primary health care approach brought forward by international organizations further initiated a movement in medicine more towards the socio-environmental model of health. This approach brought a traditional break through that social, economic and environmental determinants were far more important for the health of people than medical care. The WHO (1978) primary health care approach proposed "essential health care is based on practical, scientifically sound and socially acceptable methods and technology, made universally acceptable and available to individuals and families in the community at a cost the community and country can afford to maintain at each stage of their development in the spirit of self-reliance and self-determination". Walt and Vaughan (1981) have discussed that this signaled a move away from a paternalistic approach of health care to a more holistic approach involving empowerment of people and consideration of social justice and equity. There is increasing recognition that patients are not always passive as they are regarded in the traditional biomedical model, and indeed often take an active role in their treatment. Interpretative sociology has developed a view that people act as agents rather than being the merely the products of the contexts in which they live (Burry, 1991). Health and disease are closely interrelated as discussed by Locker (1997), those who have pathological lesions experience feelings of ill health, but he argued that it is useful to conceptualize disease and health as endpoints of one single dimension, but rather as "independent dimensions of human experience". He argued that even a hypertensive patient might perceive his or her own

health as excellent. The disease might not affect the person's self-perceived health status in any way. In other words health is not only based on a bio-physical view of the presence or absence of diseases but it can be one of several factors that a person considers when assessing his/her health.

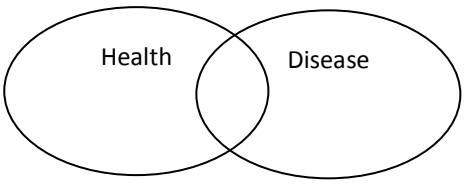

FIGURE 1.1: THE RELATIONSHIP BETWEEN HEALTH AND DISEASE (LOCKER, 1997)

Bury (1991) has reported that qualitative studies are increasingly being used to report on the lived reality of chronic illness, exploring the everyday experiences of the subjects which lie beyond indices of disability and mortality. He argued that experiences of the subject from illness are not influenced by the social context in which person lives, but by the nature of the symptoms, and their perceptions by self and others. He further argued that individuals need to make trade-offs between adherence to medical regimes and the social impact they have on daily life.

The previous paradigm, the bio-medical model, emphasized disease, whereas the new view emphasizes health, functioning and well-being. The former focused on medical care. Now the focus is on health care. The former measured disease primarily on path-physiologic disturbances, whereas measures of health now include functioning, well-being and quality of life. This paradigm shift has prompted a change in thinking about the concept of health, with health now encompassing more than the absence of disease (Patrick and Bergner, 1990).

2.2.1 CONCEPTUAL MODELS OF DISEASE

Many theories and conceptual models have been proposed to explain the components of subjective well-being. These models are multi-dimensional and assume that the quality of life is holistic in nature.

2.2.2 WILSON AND CLEARY MODEL

Wilson and Cleary (1995) proposed a conceptual model which links bio-physical concerns with social and psychological outcomes and provides a basis for exploring the associations between the two as shown in the following figure:

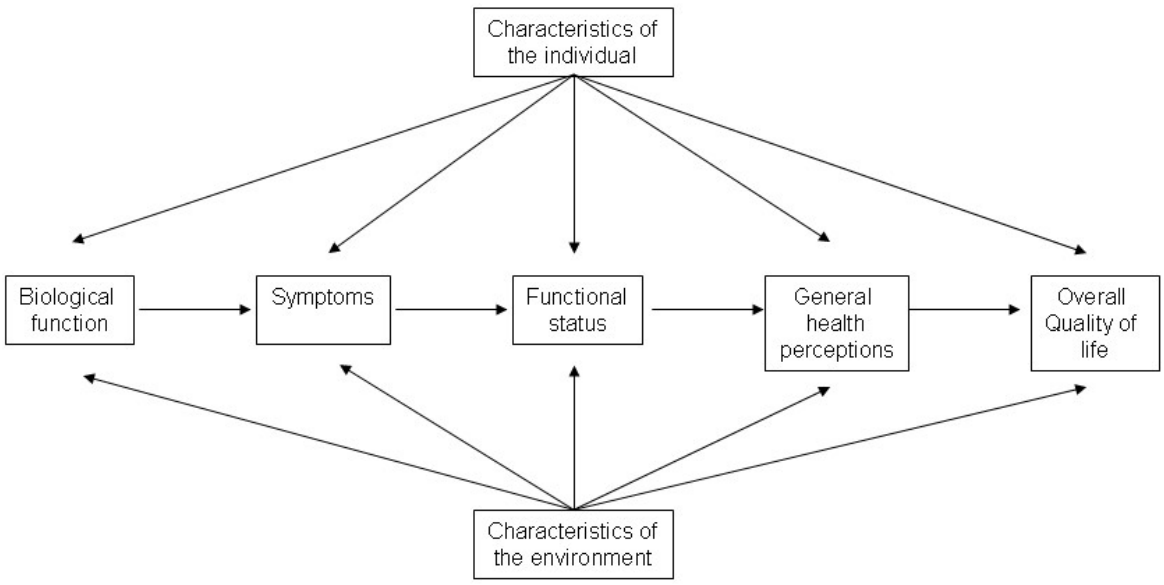

FIGURE 2.2.2: WILSON AND CLEARY MODEL (WILSON AND CLEARY 1995)

The first level of the model is that of biological and physiological factors because, they are commonly conceptualized, measured and applied in clinical routine practice. The second level is that of shifting the focus from specific cells and organs to the organism as a whole. As Wilson and Cleary (1995) have discussed because of complexity it is quite unlikely that treatments directed at biological and physiological factors alone will be fully effective in the relief of symptoms. The third level is that of functioning which measures the ability of the individual to perform particular tasks. The initiators of this model have argued that analysing the relationships between symptoms and functioning suggest that symptom and biological and physiological variables are correlated with functional but also that variation in functioning cannot be fully explained by these variations. The fourth level is that of general health perception which integrate the previous levels. The importance of these health perceptions arises from the observation that they are among the best predictors of the use of health services as well as strong predictors of mortality. The final level is that of overall quality of life. Locker (1996) has

described this model useful in a sense that it encompasses disease, health and quality of life, makes explicit the main casual relationships between them and allocates a mediating role to personal characteristics and the characteristics of the environment in which an individual lives. Locker (1996) further discusses that researchers need to understand that each of the component parts may be independent of the others and that the arrows mean "may or may not lead to". He has emphasized that exploration of such models with respect to oral conditions should be regarded as a priority.

In summary, it integrates both reductionism, the philosophical view that complex phenomenon are ultimately derived from a single primary principle and mind-body dualism, the doctrine that separates the mental from the somatic. As such it offers what Engel (1977) has called the bio-psychosocial perspective.

This conceptual model has been used in numerous studies globally to assess the relationship between the various concepts as hypothesized by the model (Wilson and Cleary 1995; Locker 2000; 2005).

2.2.3 THE CONCEPTUAL MODEL OF DISEASE-IMPAIRMENT-DISABILITY-HANDICAP

The WHO model of disease-impairment-disability-handicap (ICIDH) explores how disease may cause pain, discomfort, functional limitation which can handicap an individual physically, psychologically or socially (WHO, 1980). It provides a useful framework for considering the consequences of health and disease. Defining disease at levels of the consequences of disease is the fundamental concept behind (ICIDH). Impairment refers to any loss or abnormality of physiological, psychological or anatomical function. Disability refers to the impact of disease on the ability to carry out tasks in a manner appropriate to a human being and handicaps are the impacts that impairments and disabilities may have on a person's role that limits the fulfillment of a role that is normal for the individual.

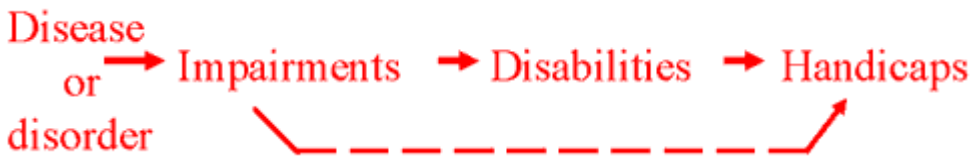

FIGURE 2.2.3: THE CONCEPTUAL MODEL OF DISEASE-IMPAIRMENT-DISABILITY-HANDICAP (WHO 1980)

Philip wood (1980) the architect of the ICIDH has said" it is not something ready-made, for use with little further thought; it is not a research tool, or a system of assessment". He further argued that it does not consider other roles in life but is an excellent starting point for trying to make sense of the experience of disease from the patient's view.

Since its publication the ICIDH has been frequently used across the world and translated into several languages internationally. The key concepts and any measures that derive from them are linked in a linear sequence going from disease via impairments to disability (WHO, 1980).

In 1997 the WHO revised and rephrased the ICIDH model with a second version of the model known as the International Classification of Functioning, Disability and Health (ICF). It is based on the integration of the bio-medical model and quality of life models of health. The ICF model includes a dimension for participation in social activities and a listing of environmental factors that are considered important for understanding the complexity of disability (Gray and Hendershot 2000), basically disability-related research suggested the need for a revision of the ICIDH framework (Badley, 1987) as critics of the ICIDH discussed that this classification presumes disable people in society as being able to do little or nothing of value (Pfeiffer, 2000). Mac Entee (2006) has discussed that the ICF has already made an impact on the way in which data concerning disability are conceptualised, collected and processed in general, as disability is now being encompassed in the model as an umbrella term representing the dynamic between person and environment.

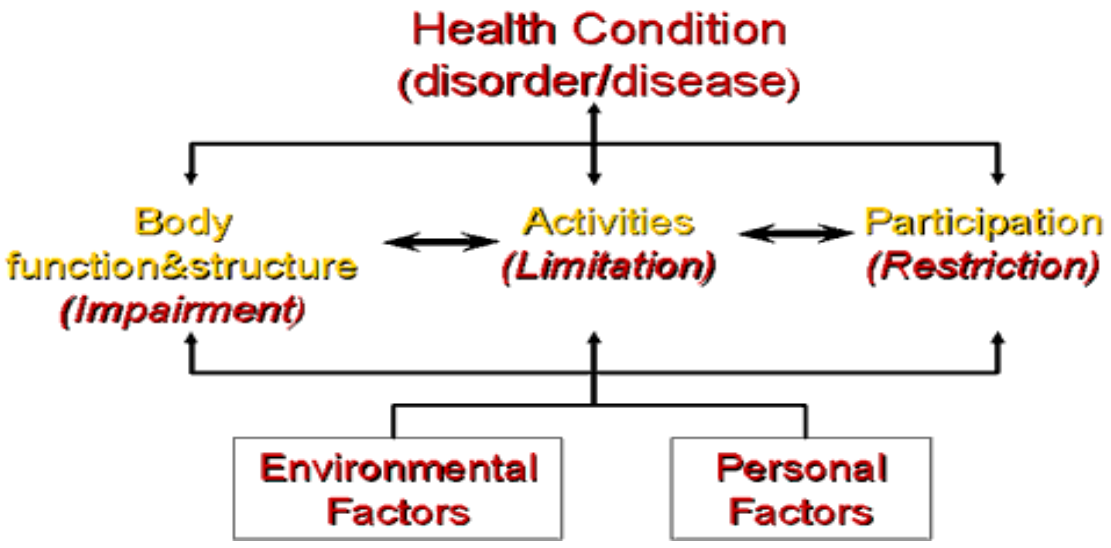

FIGURE 2.2.3.1: THE ICF MODEL (WHO, 1997)

This model has reflected biological and social aspects of health, disease, and disorders in a positive way, in terms of bodily functions and structures that act under the influence of environmental factors.

In 1988 the conceptual framework for measuring oral health status, described by Locker, illustrating causal relationships among the various domains of oral health outcomes was pivotal to the development of oral health outcome measures research in dentistry. The Locker conceptual framework is shown in the following figure:

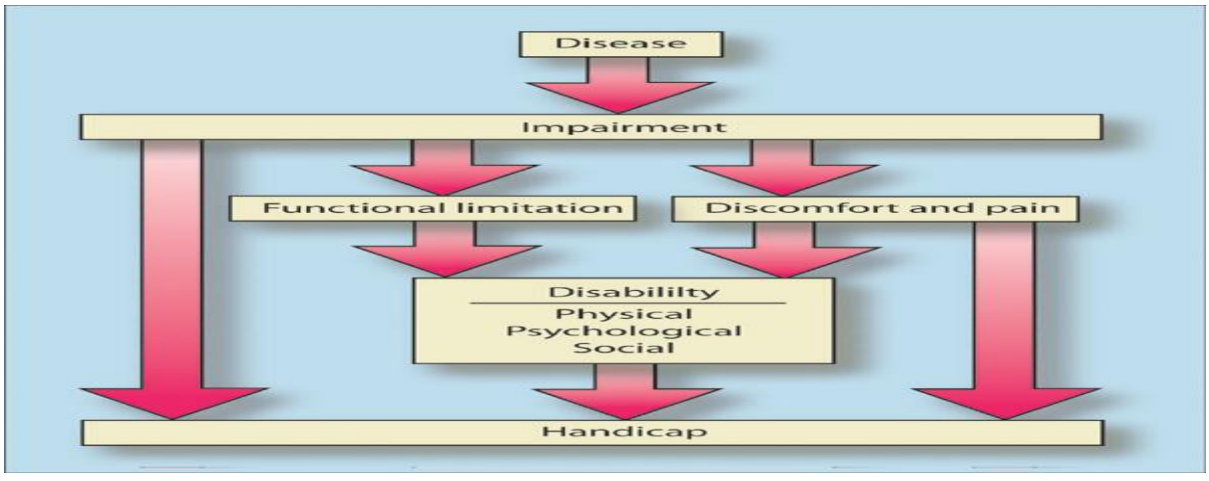

FIGURE 2.2.3.2: LOCKER CONCEPTUAL MODEL (LOCKER, 1998)

It is based on the WHO (1980) classification of impairment, disability and handicap, and attempts to capture all possible functional and psycho-social outcomes of oral disorders. By definition, people who lose teeth are impaired (i.e. have lost a body part), the other consequences are disability (lack of ability to perform daily functions like eating and speaking) and handicap (e.g. minimising social contacts due to embarrassment with complete dentures). Slade (2002) has discussed that Locker has outlined in his model that quality of life is determined by both characteristics of the person as well as non-medical factors.

These conceptual models (ICIDH and ICF) have been used in numerous studies globally to assess the relationship between the various concepts as hypothesised by the model (Locker and Slade 1994; Locker, 1988; McGrath' 2001).

In addition to these models a new model showing an association between oral health constructs has been proposed by Gilbert et al. (1998). The proposed multidimensional model was tested in a longitudinal study "The Florida Dental Care Study". In accordance with this model, studies of oral health address the following main concepts: biological and physiological variables in terms of oral diseases, symptoms, functional limitations and oral disadvantage. Within this model, oral disease and tissue damage refers to disorders at the organic level or tissue loss. Oral symptoms and functional limitation reflect the immediate consequences of disease and tissue damage for dysfunctions such as pain and the inability to chew food adequately. Oral disadvantage refers to the psychosocial and behavioural consequences of oral disease, such as difficulty in performing daily activities. The final concept of self-rated oral health reflects subjects' expressed overall evaluation, incorporating expectations, values and social and cultural background.

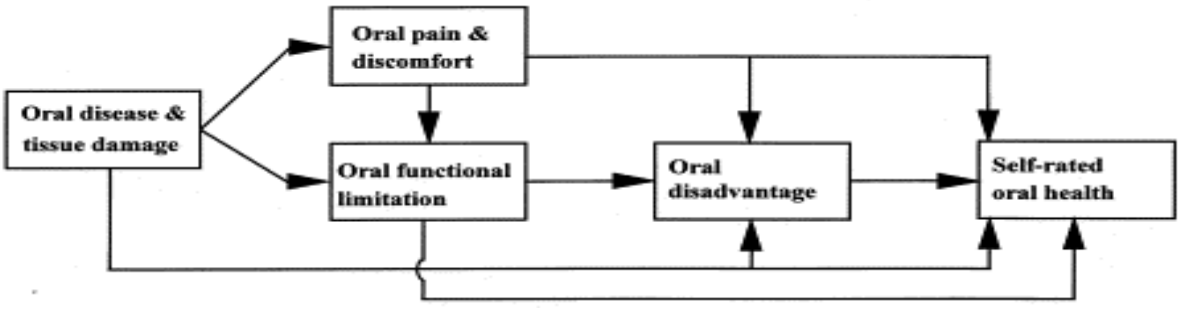

FIGURE 2.2.3.3: GILBERT MULTI-DIMENSIONAL CONCEPTUAL MODEL OF ORAL HEALTH SPECIFYING RELATIONS BETWEEN DIMENSIONS OF ORAL HEALTH (GILBERT, 1998)

This conceptual model has been used in numerous studies globally to assess the relationship between the various concepts as hypothesised by the model (Gilbert et al., 1998; Astrom et al., 2007; Kida et al., 2007; Astrom et al., 2010).

2.2.4 THE WELLNESS MODEL

The Wellness model aims at higher levels of health and wellness. It assumes that the mind affects even the simplest physical processes, such as the digestion of food (Dubos, 1979). Holman has defined health according to the wellness model as 'optimal personal fitness for full, fruitful creative living' (Goldsmith, 1972). The Wellness model has defined health as strength and ability to overcome illness, having a 'reserve of health'. Bad health can exist even though the disease is not present, just as one can experience lesser diseases and be healthy. Williams (1993) has discussed that health and illness are separate dimensions and not merely opposites in the wellness model. Neilson (1988) has discussed that this model involves progress toward a higher level of functioning, an optimistic view of the future and one's potential, and the integration of the total individual body, mind and spirit in the functioning process. Berwick et al. (1991) have discussed that this model recognizes the important linkage between mind and body that the practicing physician may overlook, as they have reported that primary care physicians often fail to recognize significant mental disorders in the patients they treat. Schroeder (1983) described that in the wellness model as that health is more than the absence of illness but also had positive dimensions such as well-being, energy, ability to work and efficiency. Greer (1983) and Dubos (1979) have described this model as a model that recognizes that very large number of diseases is healed by the body itself and health is influenced by personal feelings, energy, comfort and ability to perform. Berkman and Breslow (1983) reported a finding from studies conducted in the United States in 1965 and 1974 that health practices and social networks have broad health consequences, that is the nature and extent of social networks, such as marriage, friends, relatives, memberships of churches and organizations etc.

However, the critics of this model have pinpointed the difficulties in measuring subjective perceptions. Larson (1991) criticized it by discussing that wellness "expands the meaning of health to include happiness, quality of life, and other global matters". A

person may be perfectly happy with the medical model but may be unhappy and have a low quality of life according to the wellness model.

However, health promotion and disease prevention are a key element of this model and has raised the question whether some spiritual values are more productive than others in promoting well-being? This model has raised a question about how a physician practically can assist the patient in improving overall well-being. The Wellness model not only forces medicine to focus on the patient as a person but also focuses on promoting the positive aspects of health.

2.2.5 THE ENVIRONMENTAL MODEL

The essence of the Environmental model is an individual adaptation to the physical environment, social and other environments. Breslow (1989) described this model as meaning that health is not merely biologic elements or social role performance but is dynamic equilibrium with the environment and the capacity to live physically, mentally and socially. According to the Environmental model, health is related to the ability of an organism to maintain a balance with its environment, with relative freedom from pain, disability, or limitations, including social abilities. Abanobi (1986) has discussed that health exists when an organism works with its environment successfully and is able to grow, function and thrive. Verbrugge and Jette (1994) have described disability as lack of adaptation or a gap between one's ability and demands of the environment. Ill health is defined in terms of lack of ability to function. Greer (1986) has defined positive health in the environmental model as "the ability and will of the individual to perform needed tasks, i.e., to produce and reproduce, in an environment over the span of a life time". Noack (1987) has observed that the environmental model also emphasises on health promotion as it was the case in the wellness model discussed earlier. The Ottawa Charter for Health (developed by the WHO) has emphasized a more comprehensive environmental approach to health promotion Speller, Learmonth and Harrison (1997) have discussed that health promotion requires good public policy, personal skills, community action, supportive environments and reorientation of health services. Therefore the effectiveness of interventions to improve health cannot be judged independently of the social and political environment.

This model has been criticized by those who have pointed out that the definition of the model is so broad that these definitions are ambiguous and abstruse. Goldsmith (1972) has discussed how one operationalizes "cheerful acceptance" or "perfect continuing adjustment" to the environment.

However, Breslow (1989) has argued that health status measurement should be expanded to include the dynamic equilibrium of people with the environment and the capacity to live mentally, physically and socially, he believes that there would be a significant advancement in health status measurement if this measurement would combine the environmental and WHO models of health.

2.2.6 THE CONCEPT OF POSITIVE HEALTH

The concept of positive health has evolved over the past 40 years, beginning with Current Concepts of Positive Mental Health (Jahoda, 1958). However, the concept of positive health that has important implications and meanings in medicine (Grmek, 1966) was first outlined by Andrija Stampar (Seicpp C, 1987) who was one of the giant figures in the international public health movement of this century. He was one of the key figures in the drafting of the constitution of the WHO, personally responsible for introducing the off-quoted emphasis upon "positive health" contained in the preamble of that document. Stampar expressed his own views about the importance of the shift to positive health in the following terms "Disease is not brought about only by physical and biological factors. Economic and social factors play an increasingly important part in sanitary matters which must be tackled not only from the technical, but also from the sociological point of view. Although medicine is over 5,000 years old and modern science about 150, it is only during the last 50 years that this idea has gained ground. Health should be a factor in the creation of a better and happier life. Since health for everyone is a fundamental human right, the community should be obliged to afford its entire people's health protection as complete as possible. The preamble to our constitution represents, therefore, a great victory, embodying as it does this correct conception of public health, and thus throwing a guiding light on the long and difficult path ahead. Medical science must adopt a positive rather than a defensive attitude. Great tasks await the World Health Organization in this field and its future success will largely depend on its ability to put these ideas into practice" (Grmek, 1966). The concept of positive health was described as

"a new and revolutionary concept of health" by the editor of the Journal of the American Medical association (JAMA, 1949). The concept of positive health encompasses more than what can be ascertained through the physiological or biochemical assessment and analysis of bodily functions. Dunn (1974) has described it as the full potential of which an individual is capable of. Recent definitions of positive health include at least four constructs: a healthy body; high quality personal relationships; a sense of purpose in life; self-regarded mastery of life's tasks; and resilience to stress, trauma and change (Ryff and Singer, 1998). Each component is associated with positive health outcomes.

Rowe and Kahn (1998) have discussed that an individual who is physically fit and has healthy habits is less likely to develop a disability or die prematurely from chronic disease. Most of the measures of health status measure ill health or the absence of disease and illness. Ware (1981) has argued that when these measures are used to study sick population they seem appropriate but they have little value in measuring the health of the general population since relatively have the disease. Negative definitions of, and measurements of health status will tell a little about the health of the population (Bowling, 1997). The concept of positive health has been supported by the WHO (1993) which has recommended the development of measures of positive health because the majority of existing measures does not reflect the global definition of the WHO (1948), although this is the theoretical underpinning, explicit or implicit for development of a measure. The concept of positive health is a broader term that captures health more than the mere absence of disease-impairment-disability-handicap but implies completeness, full functioning, ability to cope, social support, adjustment and efficiency of mind and body (Thuriaux, 1988; Bowling, 1997). Lamb et al. (1988) have described it as the ability to cope with stressful situations, integration in the community, high morale and life satisfaction, maintenance of strong social support systems, psychological well- being, and level of physical fitness as well as physical health. Bowling (1997) has argued that even in disease-specific measures of health where negative measures of health are more appropriate, a more balanced scale including positive measures should also be used in order to assess outcome in relation to degrees of wellness as well as illness.

Heyrman and Van Hoeck (1993) have emphasized that with the concept of quality of life there is also a humanistic value of health in which optimal autonomy, positive strengths and positive meanings of life are central components. The positive health focus, however, calls for more, namely, the promoting of positive behavioural, environmental, and

psychosocial factors viewed as protective influences in "salutogenesis" (Antonovsky, 1987) the aetiology of optimal health and well-being. Rose (1992) outlined that a key implication of the shift toward positive health promotion is that it will require going beyond strategies targeted at high risk groups to broader goals of health enhancement for the population at large. Although the concept of positive health is clearly important, it presents several challenges (NRC, 2000) as it is not clear whether positive health is incorporated into other definitions of health- particularly those that include both current function and prognosis. Most of the evidence supporting positive health is associated with better outcomes for those with healthy bodies, high quality personal relationships, a sense of purpose, and high self-regard (NRC, 2000). Secondly, assessing positive health is difficult. Across cultures, socio economic status, and ethnic groups, people rate restrictions in activities associated with health conditions as less desirable than not having such restrictions (Patrick et al., 1985).

Researchers have considered that there is also a difficulty with the "algebra" of positive health. The current approaches regard optimal health as the condition of having no limitations on activity and being free of symptoms. This frames health in negative terms. The concept of positive health suggests that optimal health should be characterized by having a sense of purpose in life, of high quality personal relationships, and high self-regard. However, the way in which "positive" and "negative" components interact to produce a given health status has not been described (NAS, 2001).

In context of oral health Locker and Gibson (2006) have defined positive health as the absence of negative health states, positively worded items, positive outcomes of oral health, a set of psychological and social attributes, and positive outcomes of chronic conditions such as oral- and craniofacial differences. McGrath et al (2004) claimed that positive and negative health states and experiences are distinct, in that "the absence of a negative does not necessarily imply a positive and a positive state can coexist with a negative state" .The QHQoL-UK developed by McGrath (2001) has attempted to asses both positive and negative effects of oral health. However Locker et al. (2007) after a study to assess the performance of negatively and positively worded items in questionnaires to measure child and parent perceptions of child oral health-related quality of life have raised a question. Results have shown that the performance of the positively worded items was unsatisfactory and their use of oral health-related quality of life

indexes, either to reduce response set or assess positive oral health still needs further research.

2.4 Measuring Health Outcomes

Measuring health outcomes can help to assess health care in many ways such as identifying patients need, screening for their psycho-social problems, to monitor patient's progress and to determine choice of treatment.

2.4.1 Definitions of health outcomes

The usually cited definition of health outcomes is that of Donabedian (1985), who defined health outcome as a change in patients' current and future health status that can be attributed to antecedent health care. In the narrowest sense "outcome" refers to what patients experience as a result of disease and its treatment (Weeks, 1997). Lohr (1988) defined it as the research on the management of patients that asks what treatment is effective and for whom in more realistic settings than those used in randomized, controlled trials.

The emphasis of this study technique is on an array of outcomes beyond simple restoration of normal anatomic relationships and particularly on end points emphasizing the patient's assessment of pain, function, quality of life and satisfaction with the results of the interventions (Lohr, 1988).

2.4.2 The origins of the medical outcomes movement

During the last decade there has been an explosion of interest in measuring the outcomes of medical care. The science of measuring outcomes and of integrating that process into the routine care of patients has come to be known as the outcomes movement (Weeks, 1997). The evaluation of health care interventions is an integral part of evidence based medicine. As observed by Cochrane (1972) "we should be delightfully surprised when any treatment at all is effective, and we should always assume a treatment is ineffective

unless there is evidence to the contrary." Patrick and Chiang (2000) have discussed that health outcomes represent a major piece of evidence on which these value judgments can be made, along with all the other personal, economic, cultural, and socio-political considerations that influence decisions. They further emphasize that health outcomes research brings into clearer focus the essential role of patients and consumer perspectives in assessing effectiveness of health services.

Several factors have led to growing interest in measuring outcomes of medical interventions. If we look deep into history Rosser (1993) describes the evolution of medical audit from the time of Heroditus in 450 BC. In the 1830s, a physician named Pierre-Charles-Alexandre Louis started a group in Paris that discussed the use of statistics to examine patterns of medical care. In the mid of 1800s Nightingale (1863) maintained detailed records of the patients to changes in interventions and developed a new statistical procedure for tracking such data, by using mortality and morbidity data she demonstrated a lower standard of care at the hospitals. In the early 1900s, E.A. Codman, a Boston surgeon developed and implemented his quality assurance system, termed "the end result system". He stated that to "effect improvement, one must admit and record lack of perfection." He established one of the first peer-review systems (Codman, 1916). The first continuous monitoring and publicising comparative clinical outcomes as a measure of performance was in the US and came from management (Russell, 1998). Hospital death rates for Medicare patients have been published by the Health Care Financing Administration since 1986 (Bowen and Roper, 1987). For improving outcome in the Coronary artery Bypass Grafting, the New York state Department of Health published hospital mortality data since 1992 for surgeons performing at least 200 operations per year (Chassin et al., 1996). However, every effort was made to guide media on how to interpret the results accurately.

2.4.3 HEALTH OUTCOME MOVEMENT IN UK

In the UK the creation of an internal market and the division of health care into purchaser and provider organisations directly influenced the evaluation of health care and health outcomes research (Secretary of State for Health 1989). The measurement of health outcomes of clinical interventions has become a cornerstone of health services research and is linked to the assessment of the appropriateness of health care interventions (Brook,

1990). In 1989 the White paper 'Working for Patients' (NHSME, 1989) outlined changes which eventually directed purchasers to obtain evidence of cost-effectiveness in the contracting process. The NHS reforms of the early 1990s focused for the first time on "health gain" (NHSME, 1991). Clinical audit was introduced (NHSME, 1993) "it involves systematically looking at the procedures used for diagnosis, care and treatment, examining how associated resources are used investigating the effect care has on the outcome and quality of life for the patient." It involves routine monitoring of the health care, thus recognizing the need for more systematic study of the relationship between health care and outcomes. Hammmermeister et al. (1995) described health outcomes are central to the definition of the quality of care, the growing interest in the assessment of health outcomes reflects the increased awareness of the variations in the effectiveness of interventions and quality of care (Peter, 1998). In England a Central Health Outcomes Unit was created to develop and test population outcome measures which would assess the extent to which health gain was being achieved (Lakhani, 1996). Also in Scotland, a Clinical Outcomes Indicator Group was created which has published four rates of inter-area comparisons of a range of indicators on such topics as rate of teenage pregnancy, and 30 day case fatality in hospitals for a range of conditions or operations (CRAG, 1996). However Kendrick (1996) has discussed that a "health warning" was issued for the media and other readers that no results should be derived from these data and they were not league tables in any sense of ranking performance. Frater and Dixon (1993) in a survey of UK purchasers in 1993 found that the purchasers wanted clinical outcome measures for several reasons: to indicate what clinical care was worth purchasing: to help to choose which provider unit to purchase care form and to monitor the contracts. Russell (19980 reported that the main pressure to use outcome indicators as the basis of judging performance in the UK is interlinked to value for money in the NHS and comes from central government rather than from the professions.

In the White Paper, 'The New NHS' (NHS, 1997) the Government outlined a new agenda in which commitments were promised to improve quality standards of the care, efficiency, openness and accountability in the NHS. It promoted the use of national standards for services supported by consistent evidence based guidelines to raise quality standards. To improve quality and performances in the NHS the government has introduced a series of initiatives and monitoring systems. Clinical Governance was introduced to provide a mechanism for quality assurance of clinical decisions (NHS, 1999). In 1998 the National Institute for Clinical Effectiveness (NICE) was established.

The motive behind this was to provide consistent guidance to clinicians about the clinical and cost effectiveness of new and existing interventions (NHS, 1998). To tackle un-acceptable variations in quality across the country the Department of Health has proposed a series of National Service Frameworks to define standards for service provision (NHS, 1998). The Performance Assessment Framework was designed to encourage the NHS to address performance across the whole range of its activities (DOH, 1998). It judges the quality of service being provided and focuses on key areas out of which health outcomes and patients and carer experience are one of the key issues. A statutory body The Commission for Health Improvement was also set up to provide independent assessments of local actions to improve quality (NHS, 1998). This commission ensures that clinical governance arrangements are in place and that NICE guidance is implemented throughout the NHS, as well it checks the implementations of National Service Frameworks. The use of clinical indicators and high level performance indicators have helped NHS organizations to compare performance with similar organizations and with the national average, which helps to identify areas for further investigation and possible action, share information and helps to develop good practice skills to achieve best results for the consumers and provides information to the users about health service performance (DOH, 1999).

The measurement of outcomes is a key and can be used to evaluate therapeutics, clinical management strategies, the general population health, organizational performances, and health care policy (Karen, 1999). By incorporating the measurement of outcomes in the evaluation of competing therapies and organizational structures, clinicians, researchers and administrators can determine optimal strategies for patient care (Karen, 1999).

The traditional outcomes measures are becoming less acceptable, as high treatment cost are rising and variance in the subsequent health status (outcomes) of the patient population appears to be high (Ireson et al., 2001). Now most technologies aim to prevent , cure or alleviate the effects of diseases and conditions which do not threaten life (DOH, 1992) so there has been a shift from strictly outcome measures (the traditional "five Ds" -death, disability, dissatisfaction, disease, and discomfort) to include factors related to health status, functional status and quality of life (Lohr, 1988). Now a day's many interventions have little effect on mortality (Bowling, 1997). Qualitative studies are being used to report on living realities of chronic illness, exploring the diversity of everyday experience which lies beyond indices of disability and mortality (Burry, 1991).

There has been a shift in attention from acute illness to chronic disease, because of the advancement in medical technologies so the ultimate goal of therapy is to alleviate symptoms and to improve functional abilities of a subject (Wenger et al., 1984). In the elevation of treatment outcomes in chronic disease a measure of outcome needs to be able to detect even small changes in physical and mental health (Guyatt, 1987). Jenkinson et al. (1994) have pointed towards the issue that relying on clinical measures has a very limited value in evaluation of the effectiveness of treatments. Gordon et al (1998) have proposed a table for comparison of features between traditional clinical research and outcomes research in a workshop on outcomes research, in which the essential feature of outcomes research is the central role of patient centred and policy relevant outcomes.

TABLE 2.4.3: A COMPARISON OF FEATURES BETWEEN TRADITIONAL CLINICAL RESEARCH AND OUTCOME RESEARCH

Traditional clinical Research	**Outcomes Research**
Efficacy	Effectiveness
Mechanisms of disease	Impact of disease on the patient
Experimental	Observational
Feasibility	Cost-effectiveness
The effect of biochemical and physiological factors	The effects of socioeconomic factors on bio physiological outcomes
	Patient-centred outcomes
Disease-centred	Patient-and community-centred
Provider-oriented	Consumer-oriented
Inventing technology	Assessing technology
Drugs and devices	Processes and delivery of care
Methods from the "social "science	
(Physics,biochemistry)	(economics,social and behavioural sciences,epidemiology)

(Gordon et al. 1998)

Gordon et al. (1998) have discussed how traditional clinical research explores the mechanisms of disease through their biological manifestations; outcomes research studies the effect of treatments on end points important to patients and society. Traditional clinical research variables might include blood pressure, tumour size and so on whereas outcomes research would include survival, quality of life, satisfaction with care and cost.

2.4.4 THE EMERGENCE OF PATIENT- CENTRED OUTCOMES

In recent years patients have become increasingly involved in treatment decisions (NHS, 1999). Patients are the best informant about symptoms, feelings, and the ways in which illness affects what is important to them (Mayou and Bryant (1993). Relman (1988) has classified the revolution in medical care in three stages: the first one was the "era of expansion" of health services from the 1940s to through the 1960s and was followed by the "era of cost containment" beginning in the 1980s followed by the "era of assessment and accountability" beginning in the 1990's, however paralleling these changes was an evolving shift from a provider-centred model of medicine to patient-centred health care. Patient–based outcomes and greater accountability therefore become more relevant and important. It can be argued that using the patients' perceptions of outcomes is the most fair and ethical approach, as it puts the patient's interest first as the aim of medical care is to do what is in the best interest of patients (Patrick and Erickson, 1993).

The most important manifesto about outcomes research which clearly directed the attention towards patient-centred measures was Paul Ellwood's 1988 article in The New England journal of Medicine. The focus of the article was to alert physicians to a "technology of patient experience" by which they were going to be evaluated whether they like it or not "The intricate machine of our health care system can no longer grasp the threads of experience….. Too often, payers, physicians, and health care executives do not share common insights into the life of the patient …. The problem is our inability to measure and understand the effect of the choices of patients, payers, and physicians on the patient's aspirations for a better quality of life" (Ellwood, 1988, p. 1550). He clearly indicated that the object of medical science is now the patient's life rather than the patient's body. He further reflected that if physicians failed to demonstrate outcomes that mattered to patients and payers, budgets would be further squeezed. "Without compelling information on quality of life, the bottom line will continue to be money". Ellwood (1988) warned physicians that they risk losing scientific control of their profession if they do not heed the call to patient-centred outcomes. Patient-centred outcomes are viewed as the ultimate outcomes of medical care with patho-physiology only providing surrogate measures of these (Guyatt and Cook, 1994). The patient's outcome has been defined as measures of the physical and physiologic, psycho-social, and functional consequences an individual experience with health and illness by Mitchell et al. (1997).

A driving force in the transition to more patient-oriented measure has been the ever-increasing voice of consumers in the definition of quality (Schwarz et al., 2001). The UK government has promoted the involvement of patients in planning and evaluating care. In 1983, the National Health Service Management Inquiry (DOH, 1984) known as the Griffiths' report was published which recommended that information about patients' experiences and perceptions be gathered to demonstrate how well the service was being delivered locally. The principle aim of the report was to deliver and plan services in response to such information. The 1989 White Paper 'working for patients' (NHS, 1989) aimed at making the NHS more responsive to patients' need. In 1991 the Patient's Charter (DOH, 1991) was launched which focussed on public involvement for planning of health services, it introduced national standards (e.g. respect for privacy, dignity). The Patient Charter was updated in 1996 (DOH, 1996) with greater emphasis on patient involvement in decision making. The call for an acquisition of the "experience and perceptions" of patients has subsequently developed into a call for a patient-centred service (Welsh Office, 1993). The White Paper 'The New NHS: Modern and Dependable' (DOH, 1997) committed the NHS to carry out an annual national survey that would allow systematic comparisons of the experience of patients and their carers over time and between geographical variations. The principle aim of the paper was to monitor the delivery of quality standards locally, in line with the framework set out in the White Paper 'A First Class service' (DOH, 1998). The survey enabled local managers and health professionals to take on board the views of consumers of the services to improve the services. Part of the survey looks in depth at patients' experience in selected areas. The Patient Partnership Strategy (DOH, 1999) was also adapted to improve service quality by providing patients with information enabling them to make informed decisions about their health and health care. In 2000 The NHS Plan defined a ten year programme of modernisation of the NHS. At the heart of the NHS Plan is a vision of a service 'designed around the patient'. In this document chapter 10 "Changes for patients" has described a range of initiatives to improve patient information, patient choice and patient and public involvement in the NHS. These include:

- A new patient advocacy and liaison services (PALS) - NHS provision of accessible support, advice and information to patients and carers.
- The creation of a patient forum in every NHS trust to provide into how services are run.
- A requirement for NHS trusts to seek patient views on their services and publish an annual prospectus.

- Better information about local services to inform patient choice.
- Expansion of the Expert Patient Programme. And
- A requirement for letters between clinicians about the care of individual patients to be copied to their patients.

In 2000 the Scottish Executive published "Our National Health; A plan for action, a plan for change" which aimed to build a service 'designed for involving users' where 'people are respected, treated as individuals and involved in their own care; where individuals, groups and communities are involved in improving the quality of care, in influencing priorities and in planning services'.

These are the biggest changes to face the NHS since it was set up. Making them happen means the government has to prioritize. It has decided to: Pinpoint the changes that are most urgently needed to improve people's health and well-being and deliver the modern, fair and convenient services people want.

In 2001 Section 11 of the Health and Social Care Act placed a new duty on the NHS institution's to make active arrangements to involve and consult patients and publics in planning services, developing and considering proposals for changes in the way those services are provided and decisions that affect how services operate.

The Bristol Royal Infirmary Inquiry report (2001) also emphasized the role of patient and public involvement in building a more open, responsive and safe health services. The government accepted the report which included the principles that 'patients and the public are entitled to be involved wherever decisions are taken about care in the NHS' and 'the involvement of patients and the public must be embedded in the structures of the NHS and permeate all aspects of health care'.

Shifting the Balance of Power was launched in April 2001 by the Secretary of State for Health. It launched the NHS Modernization Agency as the lead organization in reforming the way the NHS works. The aim was to design a service that puts both patients and staff at the heart of the NHS. Its aim was to offer a patient service that was faster, more convenient and offer more choice and gave greater authority and decision making power to patients and frontline staff. The main feature of the change has been to give locally

based Primary Care Trusts the role of running the NHS and improving health in their areas.

Improving Health in Wales (2001) also sought to ‘enter into partnership with the people of Wales so that each citizen and each community is helping to play a role, directly or through bodies representing them, in the development of health policy, the setting of aims for the NHS, the improvement of health and well-being and the narrowing of health and social inequalities’.

In April 2002, Strategic Health Authorities were created covering an average population of 1.5 million; the main functions of the new Health Authorities include supporting Primary Care Trusts and NHS Trusts in delivering the NHS Plan in their area and building capacity and supporting performance improvement across all their local health agencies. In October 2002 the 28 Health Authorities received their 'Strategic Health Authority' status. All local NHS organizations became part of a single structure and held to account through their respective Strategic Health Authority. The primary Care Trusts took full responsibility for the health of their local population. Patient Advice and Liaison Services (PALS) started functioning and Independent Complaints Advocacy Services (ICAS) were also established.

In 2003 the national choice consultation, ‘Building on the Best-Choice, Responsiveness and Equity in the NHS’ emphasized the links between individual patient choices, service responsiveness and equity of provision. Patient and public involvement forums were established in all NHS trusts and the Commission for Patient and Public Involvement started functioning.

The Government's three year priorities and planning framework for 2003-2006, which set out the timetable of work for NHS organizations during this period, identified national priorities and targets which organizations need to build into their local plans. It included the national priority of improving the overall experience of the patients. The document stressed the role of Primary Care Trusts in creating local plans that take account of patient and public knowledge as well as professional knowledge. The publication of “Creating a Patient-Led NHS, Delivering the NHS Improvement Plan” in March 2005 described these changes as “The ambition is to move from a service that does things to

and for its patients to one that is patient-led." This brought more choices for patients, led to a strategic shift in primary care and practice based commissioning.

Equity and Excellence: Liberating the NHS (2010) has stated that patients will be at the heart of everything we do. So they will have more choice and control. Patients will be in charge of making decisions about their care. Success will be measured; there will be a relentless focus on clinical outcomes and it will bring more empowerment to health professionals. It states that" Providers will be paid according to their performance. Payment should reflect outcomes, not just an activity, and provide an incentive for better quality."

The passing of the Health and Social Care Act 2003 laid the basis for a radical reorganisation of NHS dentistry, the central aspect of this being a new contract for GDPs, which took effect on 1 April 2006. Remuneration of dentists was no longer based on the "item of service" principle – dentists began to be paid per course of treatment provided; and they were required to hit a target, expressed in "Units of Dental Activity" (UDAs).In England the Primary Care Trusts (PCTs) were responsible for contracting locally with dentists to provide services, as part of PCTs' "commissioning" role. In August 2007 the DOH published 'NHS Dental Reforms: One year on', in which it stated that dentists are more focusing on a preventive approach dental access had stabilised and PCTs were now able to begin building on this more secure basis, identifying local need and commissioning new services appropriately. However, reports by the Citizen's Advice Bureau, Which? And the Commission for Patient and Public Involvement in Health have all found significant continuing problems with access.

In July 2008 the House of Commons Health Committee reported that access to dental services was deteriorating as well as also raised the fear that dentists were under treating as was evident in a large drop in the number of complex treatments being provided and of an increase in the number of tooth extractions.

Professor Jimmy Steele, commissioned by the government in 2009 in his independent review of NHS dentistry is clearly discussing that just as health is the desired outcome of the rest of the NHS, so health should now be the desired outcome for NHS dentistry, while good oral health and the quality of the service should be the benchmarks against which success is measured. He has criticized "the restorative cycle" that if we don't look

at the outcomes of treatment it will be difficult to escape the cycle of intervention and repair that is the legacy of a different age. His review findings called for dentists' contracts to encompass capitation and quality.

The new contract pilots have been designed in consultation with a national steering group made up of representatives of the profession and patients, together with NHS managers. Based on registration, capitation and quality, the new contracts currently being piloted have three main objectives:

- improve the quality of patient care
- increase access to NHS dental services
- improve oral health, especially the oral health of children

The new government wants dentists to be paid according to the actual health outcomes they secure for patients, not for meeting targets for the procedures they perform.

2.5 ORAL HEALTH NEEDS ASSESSMENT AND MEASURES OF HEALTH RELATED QUALITY OF LIFE

The concept of need is the core of health planning (Sheiham, 1995). Health needs assessment is a systematic approach attempting to ensure that health services uses its resources to improve the health of the population in the most efficient way (Scrivens et al., 1985; Hunt et al., 1986). The traditional approach based on professional judgment to assess for need of services has been challenged in recent models (Engel, 1977). Modern medicine is slowly beginning to recognize the importance of the perspective of the patient in health care and monitoring the quality of medical care outcomes. Asadi et al. (2004) have argued that more investigators are needed to understand the importance of the inter-relationships among health needs, satisfaction and quality of life. Sheiham (1995) has challenged a common assumption in the organization and provision of health services, including the dental health services, is that the need for health care can be objectively determined by professionals. As he has discussed that the definition of any given state of ill health has become open to much wider interpretation than in the past. Health care needs now extend beyond a narrow clinical interpretation to issues like:

a) The impact of ill-health on individuals and on society.

b) The degree of disability and dysfunction that ill health brings.

c) The perceptions and attitudes of patient themselves towards ill health.

d) The social origins of many common illnesses.

(Taskos and Sheiham, 2005).

These factors influence the utilization of health services and ultimately the effectiveness of treatment. The above key concepts need to be considered in the process of planning health services (Sheiham, 1995).

2.6 The concept of Quality of Life and Health-related Quality of Life

The term quality of life (QoL) was first listed in Index Medicus in 1966 (Berger, 1989). Although many observers date the official beginning of the use of QoL and related concepts in health care to 1947, when the WHO defined health as a state of physical, mental, and social well-being rather than simply as an absence of disease or infirmity (Spitzer, 1987). The term quality of life and more specifically, health related quality of life (HRQoL) relate to the psychosocial aspects of Engel's model of medicine (Kaplan, 1990). It is interesting to note that the studies of behavioural outcomes in medical research date back to the 1960's and earlier as a great deal of research was carried out in the fields of Gerontology, Oncology and Psychiatry (Gurin et al., 1960; Bradburn, 1969), articles on QoL in the biomedical fields were quite rare at that time (Kaplan, 1990). The term QoL has been used in a variety of ways in medical literature. QoL is an elusive concept approachable at varying levels of generality from the assessment of societal or community well being to the specific evaluation of the situations of individuals or groups (David et al., 1995). Liu (1976) stated that there were as many quality of life definitions as people, emphasising the axiom that individuals differ in what they find important. The term quality of life when referring to how health affects the QoL has led to a great deal of confusion. Annas (1990) has argued that in view of the multitude of definitions and usages of the term quality of life it is so misused that it should be expelled from our word list altogether. The term quality of life has been characterised as unclear, unstructured and ethereal (Locker, 1999). Abeles et al. (1994) have reported that anyone who has

attempted to review the literature on quality of life will realize that there are many different approaches to this issue, many definitions (some objective and some subjective), and many ways of operationalizing and measuring the concept. In spite of 50 years of research, a conclusion has been reached that the concept has meaning only at a personal level (Abeles et al., 1994). Calman (1984) has defined it as "the difference, or the gap, at a particular period of time, between the hopes and expectations of the individual and that individual's experience". Gill and Feinstein (1994) defined quality of life rather than being a description of a patient's health status, as a reflection of the way that patients perceive and react to their health status and to other non-medical aspects of their lives. Walter and Shannon (1990) described the current interest in quality of life in the developed world ranging from current concepts for the environment to the marketing of the products we buy, and in the evaluation of the benefit-burden ration involved in medical treatments. Globally, quality of life as an outcome indicator has added to social, as well as health service programme development (Department of Health and Social security 1989). A definition of quality of life which is consistent with the health promotion theory and practice was developed by the centre for Health Promotion at the University of Toronto. It states "quality of life is concerned with the degree to which a person enjoys the important possibilities of life" (Raphael et al., 1994). Locker (1997) has discussed that this definition is different from the objective based approaches which define quality of life in terms of the possession of certain attributes such as adequate income, social support ad meaningful work. He further discusses that this definition respects that autonomy of the individual and acknowledges that patients can provide information about what is in their own best interests. Farquhar (1995) reviewed a range of quality of life definitions and developed a typology which distinguishes between global, component and focused definitions. Global definitions express quality of life in general terms such as degree of satisfaction with life; component definition breaks down quality of life into specific parts such as health, satisfaction with life and psychological well-being: and focused definitions focuses on only one or two of the range of possible component parts. Fitzpatrick et al. (1998) have discussed a linkage between all these definitions and have discussed that they all address aspects of the patient's subjective experience of health and the consequences of illness, they all elicit perceptual information from the patient. However, Hunt (1997) has addressed an issue against using quality of life as an outcome which can influence patients' lives, but that then "soliciting of patients' perceptions of their health state and functioning" should continue to be an important component of outcomes research.

Fitzpatrick et al. (1998) have discussed that the term quality of life seems inappropriate and misleading as it suggests an abstract or a philosophical set of judgments relating to life in the broadest sense i.e. factors outside of the person such as living standards, political or physical environment, the vast majority of so called quality of life instruments do not address these wider aspects and as such the term quality of life seems inappropriate. Levis (1987) has argued that the term QoL and HRQoL should not be used interchangeably and has discussed to "distinguish those features of quality of life which will yield to medical influence from its other features which depend upon economics, politics, or culture within broader society… otherwise quality of life may become so penalized that it will lose its original meaning, intent, and even possible usefulness". Hornquist (1982) argued that human needs are the foundations for quality of life and that the quality of life is the degree of satisfaction of those needs for example, physical, psychological, social, activity, marital and structural. Calman (1984) defined it as in relation to health as difference between reality, or the perception of reality, and expectations. Cohen (1982) pointed that the simple listing of quality of life domains is not a satisfactory way of measuring quality of life because it is unknown whether all important domains have been included. Rosenberg (1992) has argued that the psychometric translation of quality of life into components such as emotional status, social interaction, economic status, health status and physical capacity, while incorporating the multidisciplinary nature of human beings, does not capture their subjectivity. He further argued that hermeneutic thinking should be introduced into modern medicine, so that a naturalistic concept of mankind is presented along with a concept of the human being as a self-reflective individual responsible for their own actions. Bowling (1995) has argued that the perception and achievement of quality of life are dependent on an individual's preferences and priorities in life. Edlund and Tancredi (1985) have discussed that the meaning of the concept of quality of life is thus arguably dependent on the user of the term, their understanding of it and their position and agenda in the social and political structure. Campbell et al. (1976) have criticized this term "the quality of life is a vague and ethereal entity; something that many people talk about, but which nobody very clearly knows what to do about".

However, the evidence is there that includes health as a dimension of quality of life. Research since the early days of social indicators to the present day does suggest that health is among the most important areas of life and quality of life as suggested by prominent researchers (Rokeach, 1973; Kaplan, 1985; Bowling, 1995; Farquhar 1995).

Locker (1997) has also discussed the relationship between health and quality of life. He has elaborated that in some definitions and measures, the two are synonymous, so that measures of quality of life are indistinguishable in terms of their constituent domains from measures of health. He further discusses that there is increasing recognition that quality of life refers to much more than health and has introduced a simple model that suggests, that while clinical conditions and health problems can impact on quality of life; it is not necessarily the case that they do so. Allison et al. (1998) have discussed that we often assume that poor health means poor quality of life; many people with chronic disabling disorders still rate their quality of life higher than the healthy. Locker (1997) further discusses that some of the recent studies of the quality of life of elderly people have also indicated, that in talking about quality of life, subjects do mention health but they do not consider it an important factor.

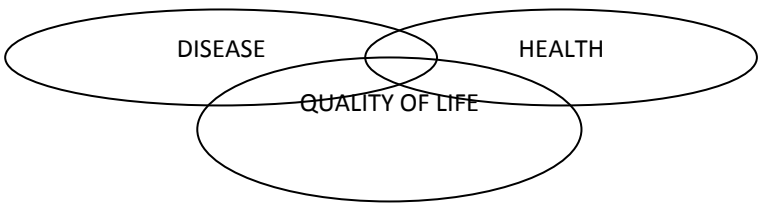

FIGURE 2.6.1: RELATIONSHIP BETWEEN HEALTH, DISEASE AND QUALITY OF LIFE (LOCKER, 1997)

In relation to health, health status is increasingly referred to as quality of life so as to narrow down its operationalization in research studies, quality of life is referred to as health related quality of life (Bowling, 1995).

2.6.1 WHAT IS HEALTH RELATED QUALITY OF LIFE?

The concept of Health Related Quality of Life is multifaceted and complex therefore defining it is a challenge (Inglhart and Bagramian 2002). They have discussed that the current definitions of HRQoL have been derived from the World Health Organization's designation of health as a state of physical, mental, and social well-being and not merely the absence of disease and infirmity (WHO, 1947). Aronson (1990) has defined it as a personal statement of the positive or negative attributes that characterize life. Bloom (1991) has defined it as a perception of disease impact that is both subjective and culturally bound. Osoba (1994) has defined it as a multi-dimensional construct encompassing perceptions of both positive and negative aspects of physical, emotional,

social, and cognitive functions; somatic discomfort; and other symptoms produced by a disease or its treatment. A newer definition of HRQoL is the extent to which one's usual or expected physical, emotional and social well-being are affected by a medical condition or treatment (Cella et al., 1996). HRQoL has been described as those aspects of quality that relate specifically to a person's health (Patrick et al., 1990). Murdaugh (1992) asserted that HRQoL reflects patients' evaluation of the effects of a disease and its treatment on their well-being. Fullerton and Gitnick (1996) stated that HRQoL is a general measure from the patent's viewpoint that includes social and psychological functioning as well as physical and physiological aspects of performance. Patrick and Erickson (1993) came up with defining it as the value assigned to the duration of life as modified by impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment or policy. Patrick and Deyo (1989) identified five concepts to define the scope of HRQoL (1) impairments, (2) functional, (3) health perceptions, (4) social opportunities, and (5) duration of life. The concepts of HRQoL have included dimensions of physical functioning, social functioning, role functioning, mental health, and general health perceptions (Ware, 1987; Fries, 1991). Other dimensions such as vitality, pain, cognitive functioning, biologic and physiologic functioning, tissue diagnoses, and patient reported symptoms have also been included (Patrick et al., 1989). The HRQoL concept incorporates both the positive as well as the negative aspects of well-being and life and itself is multidimensional, incorporating social, psychological and physical health (Guyatt et al., 1993). Lerner (1973) described the importance of measuring health related quality of life as "health is more than just a biomedical phenomenon; it involves a social human being functioning in a social environment with social roles he must fulfils".

2.6.2 THE INTEREST IN HEALTH RELATED QUALITY OF LIFE

The concept of HRQoL has rapidly evolved over the past 10 years with a significant increase in the amount of related research activity across many different populations (Osoba, 1994; Aaronson et al., 1991). The term HRQoL was first mentioned in the medical literature in 1966 (Albrecht, 1994). However, in the late 1980s, the assessment of HRQoL has gained importance and has increased rapidly, with over 100 new articles being indexed each year under this term (Muldon, 1998). However, the concept can be traced far back to Aristotle and early Greek philosophy (Argyle et al., 1995). Walter and

Shannon (1990) have discussed the interest in quality of life ranges from current concerns for the environment to the marketing of the products we buy and to the evaluation of the benefit burden ratio involved in medical treatments. Globally the quality of life as an outcome indicator has been added to social as well as Health Service Programme Development (DHSS, 1989). It has been incorporated into the World Wide Healthy Cities Programs and a group was created by the WHO known as the World Health Organization Quality of Life group (WHOQoL Group, 1993). This group has provided a definition of quality of life which also takes individuals perception and relationship to the environment into account. The group has defined it "as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, and level of independence, social relationships, and their relationships to salient features of their environment". This definition has led to the development of WHOQoL an instrument for measuring quality of life that can be used in a variety of cultural settings (Bowling, 1999).

Patrick et al. (1993) have discussed the importance of HRQoL for measuring the impact of chronic disease. In the past decade improvements in diagnostic facilities and availability of modern treatments have resulted in longer survival times for many individuals with chronic illness. Therefore to better understand the burden of disease and short and long term effects of many current treatments on patients' functioning, data based evaluations of the quality of extended survival have become important considerations for clinical trials that evaluate the effectiveness of new therapies (Ganz et al., 1992). The recent recognition of the importance of QoL outcomes in relation to chronic disease and treatment is largely the function of the three factors. First, an increased demand for data based evaluations of the quality of extended survival (Shippper, 1990; Gift et al., 1995 and Mast, 1995). Second, an emphasis on evaluations of the cost-effectiveness of treatment regimens that included adjustments for QoL outcomes (Cella et al., 1993; Barr et al., 1995; Hayman et al., 1996). Third, a need for improved understanding and identification of short and long term health outcomes and related patient service needs (Bloom, 1991). The developed world has seen an increase in life expectancy and expectations of life, and expectations of a morbidity free life at older ages, have also increased that lead to international attempts to measure health expectancy (Bone, 1992; Robin et al., 1992).The rising interest of researchers in health expectancy as opposed to simply analyzing mortality rates, has led to

focus on more positive views of health measurement in relation to health related quality of life, which is currently more fashionable than simply measuring mortality rates, disease and ill health also the debate in relation to health care cost and health gain has raised interest in health related quality of life (Normand and Bowling, 1998).Traditional clinical objective measures have largely failed to measure the wider aspects of health and thus additional measures like health related quality of measures are needed to assess the multidimensional aspects of health (Levine, 1995; Bowling, 1997). Bullingher et al. (1993) have argued that HRQoL, like subjective health status, is patient based, but focuses on the impact of a perceived health state on the ability to live a fulfilling life. From a disease or health perspective, quality of life has been said to refer to the social, emotional and physical well-being of the patient's following treatment (Greer, 1984). Kaplan (1985) has discussed that this is a double sided concept, incorporating positive as well as negative aspects of well-being and life it is multidimensional, incorporating social, psychological and physical health. Bowling (1995) defined health related quality of life by summing up all the definitions as "an optimal level of mental, physical, role (e.g. work, parent, career, etc.) and social functioning, including relationships, and perceptions of health, fitness, life satisfaction and well-being. It should also include some assessments of the patient's level of satisfaction with treatment, outcome and health status with future prospects".

This era has experienced a rapid advancement in treatment and with it a need to evaluate the benefit burden ratio involved in treatment (Walter and Shanon, 1990). Bowling (1997) has discussed that quality of life indicators can play a significant role in detecting small differences in health outcomes. Richard and Lawrence (1995) have discussed that as for planning treatment the best available evidence plays a crucial role so it is quite likely that quality of life measures can help in identifying a best approach. The HRQoL focuses on dimensions of functioning and overall well-being and current research examines ways to accurately measure complex behaviours and feelings (Wilson and Cleary, 1995). Several studies, including clinical trials have demonstrated that measures of HRQoL can be as sensitive to clinically important changes as traditional variables and can detect important differences not assessed by these traditional end points (Wilson and Cleary, 1995).

The patient empowerment to select appropriate treatment (Schneiderman et al., 1993) and discrepancies between physician and patient perception of health status and needs has also led to demand for health outcome measures. Bowling (1997) has argued that quality of life indicators can help to answer the question whether the treatment leads to a life worth

living, by providing a more patient led baseline against which the effects of the intervention can be evaluated. The Department of Health (1992) suggested that the following should be incorporated in outcome assessment: survival rates, symptoms and complications, health status and quality of life, the experiences of patients and their careers and the cost and use of resources. Brenner (1995) has pointed towards the increasing expenditure on health care costs and a need for effective planning of services based on the patient's needs and evaluations of outcomes in relevance to cost. The introduction of the purchaser provider model in the NHS (DOH, 1993) to consider outcome measures when evaluating and planning services as well as a lack of objectivity by using clinical assessment alone in planning care in the past has raised a growing concern. The health related quality of life measures can be the answer as they take into account the patients subjective experience of illness and care they receive (Bowling, 1997).

2.6.3 THE CONCEPTS AND DOMAINS OF HEALTH RELATED QUALITY OF LIFE

Patrick et al. (1988) have defined HRQoL as the value assigned to the duration of life as modified by the social opportunities, perceptions, functional states and impairments that are influenced by disease, injuries, treatments, or policy. The dimensions may be negatively or positively valued in relation to one another. They have further discussed that these domains interact with the environment and affect the prognosis for duration and quality of life. The following table contains a taxonomy of health related quality of life measures as proposed by Patrick et al. (1988):

TABLE 2.6.3: CONCEPTS AND DOMAINS OF HEALTH RELATED QUALITY OF LIFE

Concepts ad Domain	Definition/Indicator
Opportunity	
Social or cultural handicap	Disadvantage because of health
Individual resilience	capacity for health; ability to withstand Stress
Health perceptions	
Satisfaction with health function	Physical, psychological, social
General health perceptions	Self-rating of health; health concern, worry
Functional status	
Social	
Limitations in usual roles	Acute or chronic limitations in social roles of student, worker, parent, household member
Integration	Participation in the community
Contact	Interaction with others
Intimacy	Perceived feelings of closeness; sexual
Psychological	
Affective	Psychological attitudes and behaviours, Including distress and general well-being or happiness
Cognitive	Alertness; disorientation; problems in reasoning
Physical	
Activity restrictions	Acute or chronic limitation in physical activity, mobility, self-care, sleep, communication
Fitness	Performance of activity with vigor and without excessive fatigue
Impairment	
Subjective complaints	Reports of physical and psychological symptoms,
Sensations, pain, health problems, or feelings not directly observable	
Signs	Physical examination: observable evidence of defect or abnormality
	Self-reported disease
Patient listing of medical conditions or impairments	
Psychological measure	Laboratory data, records, and their clinical interpretations
Tissue alterations	Pathological evidence
Diagnoses	Clinical judgments after “all the evidence”
Death and duration of life	Mortality; survival; longevity

(Patrick and Erickson, 1992)

2.7 Measures of Health Related Quality of Life

2.7.1 Introduction

The assessment of Health Related Quality of life (HRQoL) is an essential element of health care evaluation (Coons, 2000). A number of trends in health care have resulted in the development and growing use of patient based outcome measures to assess matters such as functional status and HRQoL (Bergner, 1985; Ebbs et al., 1989). Slevin et al. (1988) have discussed that it is increasingly being recognized that traditionally bio-medically defined outcomes such as clinical and laboratory measures need to be complemented by measures that focus on the patient's concerns in order to evaluate interventions and identify more appropriate forms of health care. Interest in patient based measures has also gained importance because of rising chronic conditions where the objectives of interventions are to arrest or reverse decline in function (Bryne, 1992). Increased attention is given to patient's preference and wishes in relation to health care as well patients now expect that they need to be involved in decisions about their care and to be given accurate information to facilitate their involvement (Till et al., 1992; Siegrist and Junge, 1989). Also there is pressure for evidence to assess benefits in relation to costs of health care so that better use is made of resources being spent on health care, so there is need of such benefits as perceived by patients, careers, health care professionals and society as a whole (Epstein, 1990; Anonymous, 1991; O' Boyle, 1995). For all these reasons there is a need for much accurate and acceptable measure to assess the impact of treatments and illnesses. A number of instruments in the form of questionnaires, interview schedules, rating and assessment forms have emerged but they all have a common objective of assessing states of health and illness from the patient's perspective (Fitz Patrick et al., 1998). Guyatt et al. (1993) have outlined the modes of administration of HRQoL instruments ranging from: direct interview; telephone interview, self-completion questionnaires; and surrogate responders, if the individual is unable to answer the questions themselves for any reason. However, the most popular method is the patient completed questionnaire (Gyatt et al., 1993).

Brown (1999) has proposed guidelines for clinicians undertaking studies to measure HRQoL:

Correct choice of instruments: Is it appropriate for the study group in question? Is a generic or condition-specific instrument required? Is the instrument sufficiently responsive?

Timing of QOL measurement: Ideally, this should not be too close to the intervention that the patient confuses changes in their QOL with the effects of the intervention.

Frequency of measurement: Is the measurement once only, cross-sectional or part of a longitudinal study?

There are two main groups of instruments that may be used but each has some weaknesses and strengths, and there are advantages to using both instruments in a research study (Ware, 1993; Garratt et al., 1996). A generic measure provides a summary of HRQoL and may generate a single index or a health profile whereas specific measures focus on a particular disease, condition, population or problem and are devised to measure patients' perceptions of the outcomes of health care interventions or to assess health needs (Guyatt et al., 1993). There are advantages and disadvantages of both methods , but condition specific measures are particularly useful in the assessment of oral health related quality of life (OHRQoL) where generic measures may not be sufficiently responsive to show changes as a result of oral disease or dental intervention (Locker, 1997). The existing OHRQoL measures will be discussed in the forthcoming sections in detail.

Patrick (1993) proposed a taxonomy of Health related quality of life measures:

TABLE2.7.1: A TAXONOMY OF HEALTH RELATED QUALITY OF LIFE MEASURES

Approach	Strength	Weakness
Sores for analysis		
Single index number	Represents net impact Useful for cost- effectiveness	Effects on different outcomes not possible
Profile of interrelated scores	Single instrument Effect on different outcomes possible	May not be responsive Length often problem
Battery of Independent score measurement scale	Can select relevant outcomes Wide range of outcomes Multiple comparisons scale possible	Cannot relate different outcomes to common Need to identify major outcome
Objective of application		
Generic: across conditions & populations	Broadly applicable Summarize range of Concepts May detect unanticipated effects	May not be responsive enough May not have focus of patient interest Length often problem Effects may be difficult to interpret
Specific: disease, Population, function,	More acceptable to respondents May be more responsive	Comparisons across conditions and populations not possible
Weighting System		
Utility: preference weights from patients, easier to obtain providers, or community	Interval scale Patient view incorporated	Difficulty obtaining weights May not differ from statistical weights that are
Statistical: items weighted equally or from frequency of response	Self-weighting More familiar techniques Appears easier to use	May be influenced by prevalence Cannot incorporate trade offs

(Adapted from Patrick and Erickson (Patrick 1993))

This review gives a brief overview of some of the leading generic health related quality of life instruments. Camilleri-Brennan and Steele, (1999) have discussed that there are two types of generic instruments. The first is the health profile of which the prominent examples are the Short Form 36 item Health Survey (SF-36), the Nottingham Health Profile (NHP), the Sickness Impact Profile (SIP) and the Dartmouth Primary Care Cooperation Informative Project (COOP) charts. The other types of generic measures are the health indices or preference based measures of which the prominent ones are the Quality of Well-being (QWB) scale, the Health Utilities Index (HUI) and the EuroQol Instrument (EQ-5D). The generic measures do have uses in comparison across populations and may have scope for use in economic evaluation, but they have limited ability to capture the effects of certain interventions (Guyatt et al., 1996). The most widely used generic instruments are briefly discussed in the following section to provide researchers and clinicians with up to date, practical and comparative information about these instruments.

2.7.2 HEALTH PROFILES

Health Profiles provide a selection of scores representing individual dimensions or domains of HRQoL. Coons et al. (2000) have discussed that the major advantage of a health profile is that it provides multiple outcome scores that may be useful to clinicians and or researchers who attempt to measure differential effects of a condition or its treatment on various HRQoL domains. Summary scores have been derived from some health profile instruments by averaging scales or domains (Coons et al., 2000).

2.7.3 SICKNESS IMPACT PROFILE (SIP)

The SIP was one of the first self-reported status measures available to clinicians and researchers (Bergner et al., 1981). Originally developed for use as an outcome measure in the evaluation of medical treatment, it is a questionnaire designed to assess sickness related behavioural dysfunction (Bergner et al., 1981). The original author stated that it may be used for "1) assessing the health of the population; 2) evaluating medical care programs; 3) evaluating treatment programs; 4) planning and program development; 5) assessing

individual patient's status and response to health care" (Connn et al., 1978). As it is a behavioural based self-report measure, Damiano (1996) has argued why behaviour was chosen (i) behaviours are observable and thus can be directly reported by the individual or by a proxy referring to the target individual ; (ii) treatment can affect behaviour independent of how it affects the disease; (iii) behaviour can be reported or observed whether or not the individual seeks medical care; and (iv) behavioural effects of illness are conceptually familiar and accepted by both providers and consumers of health care.

The SIP was developed over a period of 5 years as its development began in the early 1970s by generating items from reports of behaviour dysfunction from patients, health professionals, care givers and healthy individuals (Gilson et al., 1975). Subsequent field work evaluating the psychometric properties of the scale led to the present version of the SIP which now consists of 136 items that are scored in 12 categories: sleep and rest, emotionality, body care and movement, home management, mobility, social interaction, ambulation, alertness, communication skills, work, recreational pastimes ad eating (Bergner et al., 1981). Total subscale scores vary from 0 (no dysfunction) to 100 (maximal dysfunction). Scores are derived for both categories and dimensions using the same 0 to 100 possible score formula (Bergner et al., 1976). The SIP can be administered by a trained interviewer, or it can be used as a self-administered instrument. Interview administration ranges from 20 to 30 minutes, depending upon the health status of the respondent (Damiano, 1996). The SIP has been critically valuated by researchers for reliability and validity. Reliability studies indicate a 24 hour test-retest reliability of approximately 0.90 for the entire instrument and internal consistency of 0.96. Individual scale internal consistency estimates range from 0.63 to 0.3. Inter-rater reliability for the entire instrument is 0.92 and ranges from 0.72 to 0.92 for individual scales (Bergner et al., 1976; 1985; 1987).

Damiano (1996) has reported that some researchers have found the administration of the SIP to be time consuming. Deyo et al. (1983) have also pointed towards the length of the instrument and have recommended that it should be shortened to facilitate patient acceptance. However, in a study by Hall et al. (1987) the SIP was used along with two other instruments in a convenience sample of 160 patients in two Australian general practices, less than three per cent of the questions were not answered in all instruments.

The SIP has been used in the context of many health conditions, including cardiovascular, neurological, internal, pain and muscle-skeletal disorders (Damiano, 1996) as well as in assessing changes in functional status in the elderly. The SIP may not be sensitive to the more subtle and briefer impacts of oral health problems on general health status (Reisine and Weber, 1989). Reisine et al. (1989) has further reported that the SIP can effectively assess the impacts of serious oral disorders but may not be able to assess the effects of minor oral health problems.

The SIP has been adapted for use in the UK. The UK version is called the Functional Limitations Profile (FLP). The adapted version has the same 136 items, and is designed to be an interviewer administered and has the same range of scores from 0 to 100 (Patrick et al., 1985).

The SIP has been translated into seven different languages but Anderson et al. (1996) indicated that although the translation procedure appeared to have varied for the different versions, but it appears that SIP has translated well into other languages. They however, have recommended that there is a need for much more formal and systematic testing to adequately evaluate the cross cultural equivalence of the various versions.

2.7.4 NOTTINGHAM HEALTH PROFILE (NHP)

The NHP was developed in the UK. It was originally developed to be used in epidemiological studies of health and disease (McEwen et al., 1996). The NHP was designed to reflect the lay perception of health status as opposed to the professional definition of health (Hunt et al., 1986). Patients find it highly acceptable and relevant because it reflects the concerns and perceptions of the layperson (McEwen et al., 1996). This instrument was developed by interviewing lay people. They were asked to assess how they felt when they were experiencing various states of ill health.

The NHP is a brief 45 item instrument that contains two sections. The first section covers pain, physical mobility, sleep, emotional functioning, energy level, and social isolation and the second section are concerned with the effects of the experiences covered in the first section on employment, home management, interpersonal relations, socialization, sexual

functioning, hobbies and recreation. However, by refining it further the developers of NHP have recommended that part II no longer be used (Bowling, 1997). Hunt et al. (1986) has reported test-retest reliabilities over undetermined intervals ranging from .44 to 0.89 for individual scales, depending on the population studied and particular scale. The average reliability reported is approximately 0.75. The NHP has demonstrated criterion validity and sensitivity to change in patient status. Age and sex norms help the clinician evaluate individual patients (Hunt et al., 1986).

The NHP can be self-administered or interviewer administered and because of its relative brevity and simplicity (a yes-no format) it can be completed in only 5 to 15 minutes. However, no information was found regarding the equivalence of the two administration approaches (Coons et al., 2000). The brevity of the NHP is an advantage when time is at a premium or patient compliance with longer instruments cannot be assured.

The NHP has been used with different populations and including elderly persons, pregnant women, stroke patients, peripheral vascular disease patients, patients undergoing minor surgery, a general medical population, firemen and mine rescue workers (Hunt, 1984).

The NHP has been translated into several languages. Anderson et al. (1996) have argued that although there has not been a systematic comparison of the translated versions of the original, there is evidence that the basic properties of the NHP have been retained in the adaptations.

2.7.5 MEDICAL OUTCOMES STUDY 36-ITEM / SHORT-FORM (SF- 36) HEALTH SURVEY

The SF-36 health survey is a widely used health status questionnaire comprised of 36 items selected from a large pool of items used by RAND in the Medical Outcomes Study (MOS) (Stewart et al., 1992). The 36 items are distributed by the Medical Outcomes trust as the SF 36 health survey, by RAND as the RAND 36 item health survey 1.0, by the Health Outcomes institute as the Health Status questionnaire (3 depression screening items is also included), and by the Psychological Corporation as the RAND 36 Health Status

Inventory (HSI). Minor differences in scoring for the pain and general health scales are suggested by the different distributors (Coons et al., 2000). The Psychological Corporation version incorporates item response theory scaling (Hays et al., 1998).

The Medical Outcome study (MOS) was a 4 year study of health care delivery systems that analyzed the effects of provider characteristics, patient variables, and structural characteristics of health care on outcome (Tarlov, 1989). The major goal of the investigators was to develop a set of measures that could be used with a variety of populations, including both healthy individuals and persons with chronic diseases (Stewart et al., 1992). Several measures of health status and QoL were developed, ranging in size from 6 to 149 items. The MOS measures were developed with a concept of health that involved two "overarching dimensions", namely physical and mental health, which are assessed from five perspectives: (1) clinical status, (2) physical functioning/well-being, (3) mental functioning/well-being, (4) social functioning/well-being, and (5) general health perceptions and satisfaction (Stewart et al., 1992). Even though the MOS instruments come in a several versions ranging from the long version MOS Functioning and Well Being Profile (MOSFWB) which contains 149 items and it requires between 30 and 40 minutes to complete and can be used as a self-administered instrument or in person or telephone interviews. The shortest version consists only of six items and is referred to as the General Health Survey or MOS Short Form 6 (MOS SF 6). It may be useful in studies in which a rough estimate of QOL is required but in most clinical and investigative situations, this measure would probably be inadequate (Coons et al., 2000).

The MOS SF 36 is one of the most widely used versions of the MOS scales (Ware et al., 1992). The SF 36 represents a compromise between comprehensiveness and brevity. The MOS SF 36 uses 36 items to cover eight dimensions: (1) physical functioning (2) physically related role limitations, (3) social functioning, (4) pain, (5) general and mental health, (6) emotionally related role limitations, (7) vitality, and (8) general health perceptions. This measure only requires 5 to 10 minutes for most individuals to complete. Essink-Bot et al. (1997) have observed the SF 36 is the only measure that has the notion of positive health (e.g. 'full of pep').

The MOS SF 36 has shown individual scale reliabilities range between 0.77 and 0.98, and can reliably differentiate among psychiatric patients, patients with minor medical conditions, and patients with major chronic disease (Mc Horney et al., 1992).

The MOS SF 36 appears to be the most widely used version of the MOS scales because it can be administrated in a relatively short period but is still moderately comprehensive in scope. It has been translated into seven different languages. It is the instrument for which the most coordinated and systematic effort has been undertaken for international testing and adaptation (Anderson et al., 1996).

Coons et al. (2000) on their own assessment of the available literature summarized the evidence available in the literature for the health profile instruments as follows:

TABLE 2.7.5: COMPARISON OF GENERIC HEALTH OUTCOME MEASURES SF-36 AND SIP

Review criteria	Instruments		
	SF- 36 Survey	NHP	SIP
Conceptual and measurement model	+++	++	++
Reliability	+++	+	+++
Validity	+++	++	++
Respondents and administration burden	+++	++	+
Alternative forms	+++	+	++
Cultural and language Adaptations	+++	++	+

SF 36 = Medical outcomes Study 36 item Short Form; **NHP** = Nottingham Health Profile; **SIP** = Sickness Impact Profile; + = Limited; ++ = adequate; +++ = extensive.

(Coons et al., 2000)

2.7.6 HEALTH INDICES OR PREFERENCE BASED MEASURES

In the assessment of HRQoL preference based measures provide a single number, usually on a scale from perfect health (1) to death (0). This health index score represents the respondent's point in time subjective health status and incorporates a preference value or utility for that overall health state (Coons et al., 2000). The utility or preference based measures are designed specifically for economic evaluations (Torrance et al., 1972; Kaplan et al., 1987). These measures can be used to calculate quality-adjusted life-years (QALYs) to assess the cost effectiveness of interventions. These measures provide a framework for respondents to describe their health states; preference values for reporting health states are then applied from an existing multi-attribute preference to calculate the HRQoL score (Coons et al., 2000). Although most attention has been given to preference based measures because of their role in cost utility analyses to inform decisions about resource allocation, there is some research on their use as decision aids in individual patient care where patients face difficult choices between treatment options (McNeil et al., 1982). There are two basic methods of assessing the preference or utilities of the patients involved. The most direct way of assessing preference functions has been created through population based studies in which techniques such as standard gamble, time trade off and or rating scales were used to determine health state preference values (Feeny et al., 1996). The second method is in which utilities may be assessed by obtaining information from the patients in a trial by means of self- completed questionnaires that assess health status more or less in the same way as other patient based outcome measures. The patient selects items that most describe their health state. However, in this approach the questionnaire items have weighted utility scores attached that have been derived from prior survey data in which utilities have been measured from, as far as possible appropriate samples of respondents (Feeny et al., 1995; Brooks et al., 1996). Utility measures are based on the assessment of health but attempted to summarize the value of such states. However the significance of this approach of a single figure is twofold. Firstly a single index directly elicits the individual's overall preference for a healthy state. Secondly, this global preference provides a simpler figure for analyses of the net benefit in health form an intervention, compared with the main outcomes produced by multi-dimensional measures more characteristics of most other health status measures (FitzPatrick et al., 1998).

2.7.6 QUALITY OF WELL-BEING SCALE

The Quality of well-being scale also known as the Index of well-being was one of the first quality of life or health status measurement systems (Kaplan et al., 1996). Its evolution began with seminal work in the late 1960s and early 1970s and was developed to assess the dimensions of the General Health Policy Model (GHPM). Kaplan, Bush, Anderson and colleagues developed The GHPM using a decisive theocratic approach (utility analysis) to evaluate alternative health care programs from the viewpoint of the policy maker. The QWB is most useful to investigators who use the GHMP to evaluate alternative treatment or rehabilitation programs.

The QWB is a preference based weighted measure combining three scales of functioning with a measure of symptoms and problems to produce a point in time expression of well-being that runs from 0 (for death) to 1.0 (for asymptomatic full function) (Kaplan et al., 1979). This model separates aspects of health status and life quality into distinct components. These are life expectancy (mortality), functioning and symptoms (morbidity), preference for observed functional states (utility) and duration of states in health states (prognosis) (Kaplan et al., 1979). In addition, symptom/problem complexes representing health problems or symptomatic complaints that may hinder function and well-being are assessed (Kaplan et al., 1996). The current version of the QWB scale includes 26 symptom/problem complexes, whereas the developmental self-administered version (QWB-SA scale) includes 58 symptoms (Kaplan et al., 1999).

Internal consistency, reliability has been reported not appropriate for this instrument because of the nature of the QWB scale's measurement approach (Kaplan et al., 1999). However a study of test- retest reliability of both QWB scale and QWB-SA scale demonstrated the scores to be quite stable over a 1 month period (Kaplan et al., 1999).

Studies have demonstrated that the QWB scale is responsive to change resulting from treatment interventions for a number of conditions (Kaplan et al., 1996). This method has been used for health resource allocation modelling and has served as the basis for an innovative experiment on rationing of health care by the state of Oregon (Kaplan, 1993; 1994).

This instrument has been criticized for being too long and complex. The administration of the QWB requires a trained interviewer because it involves branching and probing questions. The completion time has been reported to range from 10 to 30 minutes (Bowling, 1997). The other version developed as the self-administration form known as the Quality of Well Being Self-administered (QWB-SA) version can be completed in about 10 to 15 minutes and is self- administered (Kaplan et al., 1999). This scale has traditionally been administered by trained interviewers, face to face or over the telephone (Kaplan et al., 1999). Coons et al. (2000) have argued that additional research is required to further support the equivalence of the administration methods.

The QWB scale was developed initially in US English but has been translated in other languages but no published reports were found in the translation processes used (Coons et al., 2000).

2.7.7 HEALTH UTILITIES INDEX

The Health Utilities Index (HUI) evolved in response to the need for a standardized system to measure health status and HRQOL to describe: a) the experience of patients undergoing therapy; b) long term outcomes associated with disease or therapy; c) the efficacy, effectiveness and efficiency of healthcare interventions; and d0 the health status of general populations. HUI was designed to provide a large number of detailed descriptions of comprehensive health status and to provide a HRQL summary score for each unique description. The evolution of HUI has been guided by theoretical and empirical evidence (Feeny et al., 2002). The HUI has two components (1) a multi-attribute health status classification system to describe health status and (2) a multi-attribute utility function that is used to value the measured health status. The HUI assess functional capacity rather than performance status in contrast to QWB. Three versions of HUI have been developed. The HUI has four attributes and a formula to calculate utilities (Torrance et al., 1982). The second version HUI2 consists of seven attributes and formulae for the calculation of utilities and preference values (Torrance et al., 1992). The HUI3 version has eight attributes: vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain and is considered as the most useful version (Feeny et al., 1994).

The internal consistency reliability is not assessed for the HUI. The test-retest reliability of the HUI3 was evaluated in the 1991 Statistics Canada General Social survey, Landis and Koch (1977) reported that eight of the 10 individual questions and six of the eight attributes had moderate or better k coefficients. Torrance et al. (1995) reported the face validity of the HUI supported by the fact that all levels on every attribute appeared at least once in the population health surveys, indicating that there are no attribute levels that represent non-existent outcomes.

The self-administered HUI2 and HUI3 typically take five to 10 minutes to complete. Interviewer administration typically takes three to five minutes to complete (Coons et al., 2000).

The HUI has been used in both clinical and general population surveys. It has been used throughout North, central and South America well as in Europe and other parts of the world. Despite being translated into various languages Coons et al. (2000) have reported that no published reports were found in the translation processes used.

2.7.8 EURO-QOL INSTRUMENT (EQ-5D)

The Euro-Qol was developed as a standardized non-disease specific instrument for describing and valuing health related quality of life (Brooks, 1996). The EuroQol is intended to complement other forms of quality of life measures and it was purposefully developed to generate a generic index of health. A multidisciplinary team of European researchers developed the EQ-5D in five languages (Dutch, UK English, Finnish, Norwegian and Swedish. The EQ-5D was designed to be self -administered and short enough to be used in conjunction with other measures although the multidimensional structure was one goal, but simplicity was considered a central requirement (Kind, 1996). It was intended for use in population health surveys or in conjunction with a condition targeted instrument for assessment of outcomes related to a specific health condition and or its treatment (Kind, 1996).

The first of the two parts of the EQ-5D is a descriptive system that classifies respondents into one of 243 distinct health statuses. The current descriptive system consists of the five

dimensions; mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each dimension has three levels, reflecting no problem, some problem, and extreme problem (Kind, 1996). The respondents are asked to mark one level for each of the five dimensions. The researcher then has to assign a value to that self-reported health state from a set of valuations that have been empirically derived (Dolan et al., 1995). The second part of the EQ-5D is a 20cm VAS which has end points ranging from zero (worst imaginable health state) to 100 (best imaginable health state). Respondents are asked to mark their own health on the scale. Hence, the EQ-5D produces three types of data for each patient (1) a profile, indicating the extent of problems on each of the five dimensions, (2) a population weighted health index, based on the descriptive system, and (3) a self-rated assessment of health status based on the VAS.

Van Agt et al. (1994) have reported that test-retest reliability of the EQ-5D health state valuations were stable over time. A study conducted by Dorman et al. (1998) reported intraclass correlation coefficients (ICCs) 0.8 both for the VAS scores and the population weighted index scores, suggesting excellent reproducibility. Substantially greater ceiling effects have been reported for EQ-5D (Brazier, 1993). Hurst et al. (1997) in a study have reported good construct validity for this measure and Coast et al. (1998) have reported preliminary evidence for responsiveness to change.

As the measure was developed as short and user friendly and it takes about a minute to complete. However, Essink-Bot et al. (1997) has reported that when compared with three other commonly used generic measures, the EQ-5D had more missing data, especially for the VAS item (6.7%).

The official EQ-5D translations undergo a very systematic and in depth process (Coons et al., 2000) but the other versions which have been used have been reported to be not approved by the group.

Coons et al. (2000) on their own assessment of the available literature summarized the evidence available in the literature for the preference based measures based as follows:

TABLE 2.7.8: EURO-QOL INSTRUMENT VS QWB SCALE AND HUI

Review criteria	Instruments		
	QWB Scale	HUI	EQ-5D
Conceptual and measurement model	+++	+++	++
Reliability	++	++	++
Validity	+++	++	++
Respondents and administration burden	+	++	++
Alternative forms	+	+++	+
Cultural and language Adaptations	+	++	+++

EQ-5D = EuroQol Instrument; **HUI** = Health Utilities Index; **QWB** = Quality of Well Being;
+ = Limited; ++ = adequate; +++ = extensive.

(Coons et al., 2000)

2.8 ORAL HEALTH, ORAL HEALTH-RELATED QUALITY OF LIFE AND ENDODONTIC TREATMENT

2.8.1 INTRODUCTION

In dentistry traditionally clinical indicators have been used to measure oral health. However, this concept belongs to the biomedical paradigm. The Literature review suggests that oral health is a much broader concept than oral disease and it involves concerns about optimal functioning, social and psychological well-being thus this concept belongs to the socio-environment paradigm (Locker, 1996). The term oral health related quality of life (OHRQoL) appeared in the literature in the 1980's. The characteristics of OHRQoL are that it is dynamic, subjective and can change over time (Gregory et al., 2005).

2.8.2 ORAL HEALTH

Under the biomedical model oral health can be defined as a disease free mouth, but does it reflect the impact of the disease process on function or the well-being of the person? Cohen & Jago (1976) challenged this by discussing that the bio-medical model derived clinical indicators are just morbidity measures, and none of them take into account any dimension of function. Locker (1996) has also discussed that they look at the mouth rather than the person.

Dolan (1993) defined oral health as "a comfortable and functional dentition which allows individuals to continue in their desired role."

Yewe-Dyer (1993) defined it rather explicitly as "oral health is a state of the mouth and an associated structure where the disease is contained, future disease is inhabited, the occlusion is sufficient to masticate food and teeth are of a socially acceptable appearance".

Oral health was defined by the Department of Health UK in 1994 as the "standard of health of the oral and related tissues which enables an individual to eat, speak and socialise without active disease, discomfort or embarrassment and which contributes to general well-being".

Gilbert et al. (1998) have discussed that oral health is not limited to the management of dental caries and periodontal diseases but is a subjective experience, perceived in the context of the individual's environment. Individuals apply a multi-dimensional to assess self-satisfaction with general and oral health.

Locker (1997) has summarised oral health in the following way: "When talking about oral health, our focus is not on the oral cavity itself but on the individual and the way in which oral diseases, disorders and conditions, whether confined to the oral cavity or linked to other medical conditions, threaten or impact on health, well-being and quality of life" but has discussed further that although definitions are there that make reference to functional and social concerns there is still a focus of bio-medical approach.

The US Surgeon General's Report (2000) has described oral health as "It follows that oral health must also include well-being. Just as we now understand that nature and nurture are inextricably linked, and mind and body are both expressions of our human biology, so, too, we must recognize that oral health and general health are inseparable. We ignore the signs and symptoms of oral disease and dysfunction to our detriment. Consequently, a second theme of the report is that oral health is integral to general health. You cannot be healthy without oral health**.** Oral health and general health should not be interpreted as separate entities. Oral health is a critical component of health and must be included in the provision of health care and the design of community programs".

In summary all these definitions have looked at oral health as a broader concept than oral disease, concerning individual's optimal functioning, social and psychological well-being.

2.8.3 ORAL HEALTH-RELATED QUALITY OF LIFE

The HRQoL concept was reported in the literature in the 1960's (Murdaugh, 1996). However, OHRQoL appeared in the literature in the early 1980's despite the Cohen and Jago (1976) statement that the most important implication of dentistry is its contribution to individuals' QoL.

There is no strict definition of OHRQoL (Skaret et al., 2003). OHRQoL was initially defined by Kressin (1997) as "the impact of oral conditions on daily functioning". Locker et al. (2002) redefined OH-QoL as "the symptoms and functional and psychosocial impacts that emanate from oral diseases and disorders". Then, Inglehart (2002) defined OH-QoL more specifically as "the absence of negative impacts of oral conditions on social life and a positive sense of dentofacial self-confidence". Gregory (2005) has defined it as "cyclical and self-renewing interaction between the relevance and impact of oral health in everyday life".

However, it is important to note that available OH-QoL measures document the frequency of the functional and psychosocial impacts resulting from oral disorders, but they do not necessarily relate the meaning and significance of these impacts to QoL (Locker and Allen

2007). Locker and Allen (2007) have stated that "the claim that oral disorders affect the quality of life has yet to be clearly demonstrated". Despite research and thousands of publications the concept of ORHQoL is still without consensus regarding its definition and measurement as in a similar fashion to that of general HRQoL. Ingelhart et al. (2000) have discussed that despite diverse applications of this concept, the most important aspect of OHRQoL is to bring a patient rather than a body/mouth perspective into focus in the research field of oral health.

2.9 ORAL HEALTH-RELATED QUALITY OF LIFE MEASURES

2.9.1 INTRODUCTION

Patients, taxpayers and policy makers in health care today are looking to health care providers to evaluate medical therapies using outcome measures that are more global and incorporate the patient's own perception of their health status and functioning. Generic and disease specific oral health-related quality of life measures have been used to assess impact of oral diseases on quality of life of patients. However, disease-specific instruments are more likely to detect smaller, but important, changes in patients with a condition or disease (Allen, 2002).

2.9.2 GENERIC HEALTH RELATED QUALITY OF LIFE MEASURES IN THE ASSESSMENT OF ORAL HEALTH RELATED QUALITY OF LIFE

As the majority of the generic measures has undergone rigorous psychometric analysis Cohen et al. (1997) has argued that their use for the assessment of oral health related quality has obvious advantages over the developing oral health specific measures, Reisine (1997) has discussed that comparison can be made across conditions using the same scales enabling analysis of the relative social and psychological impacts within common oral health problems and treatments and across other general health conditions and in that way can be a useful tool in describing their relative importance to people's live as well can play a possible role in prioritizing health care expenditure. However, Locker (1999) has argued

that these measures are not oral specific and therefore not likely to be sensitive to all oral health problems. Kressin (1996) has reported that chronic pain syndromes or acute pain episodes or extended courses of dental treatments that can have severe impacts on individuals in terms of social, psychological and economic impacts can be detected by most health indexes such as the Sickness Impact Profile or the SF-36. However, the more subtle impacts of minor treatment needs, fear or anxieties about dental treatments or dissatisfaction about facial appearance may not be detected by these measures. Dolan et al. (1991) have argued that oral health should be seen as a separate construct from other health measures, but in contrast Resisine (1997) has described oral health as a part of the broader definition of general health

The Sickness Impact profile (SIP), one of the earliest attempts at developing a multidimensional, behaviourally based measures of health status developed by Bergner et al. (1981), has been used in the context of many health conditions, as well as assessing changes in functional status in the elderly but has not been applied frequently in studies of oral health (Reisine, 1997). However two studies of oral cancer and quality of life and functional status have employed the SIP with good results (Hassan et al, 1993; Langlus et al, 1994). The SIP was sensitive to cancer stage, and was responsive to change over time and to treatment type. However, Reisine and Weber (1989) validated SIP use in relation to oral health. A convenient nonrandom group of 152 patients presenting for care at a private dental practice were chosen for a study to validate SIP use in relation to oral health. The sample consisted of 48 patients presenting for temporomandibular disorders (TMD), 33 suffering from periodontal disease, 23 patients presented for denture repairs and 48 recall patients (regular six month checkup). The construct validity of the measure was assessed through relating the domain score of SIP to the four patient groups. The hypothesis was that recall patients would have the lowest impact scores as they were presenting themselves for just six month checkup. The findings indicated that temporomanibular joint patients experienced a high degree of impact; in particular the domains of well-being, social functioning and symptoms were affected. Denture patients also reported significant impacts in the SIP as their condition caused problems in home tasks, social and leisure activities. Recall patients experienced low impact thus supporting its construct validity. The investigators reported that SIP may have more limited application in assessing general oral health status; as well they raised concerns about its sensitivity in relation to minor oral

health problems and in relation to clinical oral health status (number of decayed, filled or missing teeth) (Reisine et al., 1989).

Allen et al. (1999) used SF-36 in a study to compare its validity with a disease specific oral health related quality of life measure. The oral health related quality of life measure showed good discriminative and construct validity properties, as SF-36 failed to discriminate between clinical disparate groups. The researchers further reported that SF-36 is not oral specific therefore not likely to be sensitive to oral complaints. It was concluded that a disease specific measure is of greater use in measuring outcomes of oral disorders than generic measures as in this case SF-36. The researchers further reported that these findings should be considered when health related quality of life measures are employed to target resources and used to measure the outcome of clinical intervention.

Heydecke et al. (2003) used SF-36 in a study to measure health status with generic instruments in a randomized clinical trial of treatments for oral disease. SF-36 was utilized in the study to compare its performance with an oral health specific quality of life measure among a group of senior adults receiving implant over dentures and conventional prostheses. It was concluded that SF-36 showed no significant differences between the two groups, whereas the oral health specific quality of life measure showed significant pre-post treatment differences between the groups for the role emotional, vitality and the social function scales.

Spencer et al. (2004) used EQ-5D to compare the dimensions of oral health related quality of life measures. The researchers reported that EQ-5D covered daily activities such as self-care and usual activities but failed to cover oral health specific aspects of functional limitations and physical disability as well as psychological and social aspects of disability and handicap which were covered by the oral health related quality of life measure.

Marino et al. (2008) in a study conducted on the impact of oral health on the quality of life (QoL) of Southern European, dentate older adults, living independently in Australia have reported a negative association between oral health indicators and both the oral health-related QOL and the physical component of the SF-12.

Samman et al. (2010) have reported that using the generic health approach (SF-36), there was significant improvement in mental health (MCS) only. Using the generic oral health assessment method (OHIP-14), significant improvements in QoL were also observed in patients after orthodontic-surgical treatment

Scott et al. (1999) conducted a study on high risk patients undergoing orthognathic surgery have shown that the psychosocial scale score results from the SIP were found to have a statistically significant impact on postsurgical outcomes.

Generic quality of life measures have been used in the assessment of oral health related quality of life (SIP, Sf-36, and EQ-5D). However there are concerns about their ability to measure subtle changes in oral health. However, they perform less well than oral health specific measures at assessing the impact of oral health on the quality of life (Reisine, 1997).

2.9.3 ORAL HEALTH RELATED QUALITY OF LIFE MEASURES

There is no strict definition for the term "health-related QoL" rather it is a multidimensional construct which focuses on the peoples own perceptions about the factors that can be important in every day to day living. US surgeon General (2000) report suggested in "Healthy People 2010" that it is the person's own sense of physical and mental health and its own ability to react to the factors in the physical and social environment. The US Surgeon General Report on Oral Health (2000) has noted that OHRQoL also derives from a multidimensional construct and it reflects (among other things) a person's ability to eat, sleep and engage in social interactions comfortably as well as reflects their self-esteem and satisfaction with respect to oral health.

Patrick and Erickson (1993) identified and suggested a range of multiple dimensions representing health related QOL. However it is interesting to note in the table that they have included traditional clinical measures and epidemiology indices which were criticized by the socio-medical indicators movements as their movement outlined a shift from disease centred to patient centred approach in health care. Patrick and Erickson (1993)

reported that most efforts at assessing health-related quality of life focus on six concepts as listed in the following table:

TABLE 2.9.3: CONCEPTS AND DOMAINS OF HEALTH-RELATED QUALITY OF LIFE

Domain	Characteristics
Opportunity	Social or cultural handicap,individual resilience
Health perceptions	Satisfaction with health,general health perceptions
Functional status: Social	Limitations in usual roles,integration,contact,intimacy
Functional status: Psychological	Affective states,cognitive capacity
Functional status: Physical	Activity restrictions, fitness
Impairment	Complaints,signs,self-reported disease,physiologicmeasures,diagnoses
Death and duration of life	Motality,survival,longevity

(Patrick and Erickson (1993)

These broadly defined concepts have led to generation of various approaches to the assessment of OHRQoL.

In the past five decades researchers have generated a number of patient-based instruments designed to measure health, functional status and the importance of health in daily living. These instruments include a number of oral-specific health-related quality-of-life instruments often called oral quality of life instruments (OQL). These have been designed to measure the impact of oral conditions on people's lives. The Cohen et al. (1976) paper was the initiator as they advocated the development of "socio-dental" indicators, there has been considerable methodological research leading to the development of questionnaires to measure dimensions of quality of life that relate to oral health as reported by Gift (1996). Kressin (1996) suggested that there is a need to incorporate quality of life into the evaluation of dental care, but also pointed towards a fundamental methodological problem that oral health outcome researchers had little involvement in the development or use of instruments to assess oral health related quality of life.

It is now generally accepted that the measurement of oral health-related quality of life is an essential component of oral health surveys, clinical trials and studies evaluating the outcomes of preventive and therapeutic programs intended to improve oral health as suggested by Taskoset al. (2005). The assessment of oral health-related quality of life has an important role to play in clinical practice as suggested by Locker et al. (2001).

The following table summarizes the instruments available for measuring oral health related quality of life:

TABLE 2.9.3.1: ORAL HEALTH RELATED QUALITY OF LIFE MEASURES

Measures	Original Reference
Social Impact of Dental Disease (SIDD)	Cushing et al.,1986
Dental Functional Status Index	Rosenberg et al.,1988
Subjective Dental Health Index(Rand health study)	Gooch et al., 1989
Sickness impact profile (SIP)*	Reisine et al.,1989
Dental Impact Profile(DIP)	Strauss et al., 1989
Geriatric Oral Health Assessment Index(GOHAI)	Atchison and Dolan,1990
Global Oral Health Rating	Atchison and Dolan,1990
Subjective Oral Health Status Indicator(SOHSI)	Locker and Miller,1994
Oral Health Impact Profile (OHIP)	Slade and Spencer,1994
Oral Health Related Quality of Life(OHQOL)	Kressin,1996
Short form-36(SF-36)*	Kressin,1996
Dental Impact on Daily Living(DIDL)	Leao and Sheiham,1996
Oral Impact on Daily Performances(OIDP)	Adulyanon and Sheiham,1997
Oral Health-Quality of Life Inventory (OH-QOL)	Cornell et al.,1997
Oral Health related Quality of Life (UK) (OHQOL-UK)	McGrath and Bedi,1998

* General Health related quality of life measure

These instruments are described in detail in the following section:

2.9.3.1 THE SOCIAL IMPACT OF DENTAL DISEASE (SIDD)

Dimensions measured	No. of questions	Example of Questions	Response Format
Chewing,talking,smiling, Laughing,pain,apperance	14	Are there any types of foods You have difficulties chewing?	Yes/no

(Source: Inglehart and Bagramian, 2002)

The SIDD is one of the first socio-dental indicators developed in the early 1980's. The social indicators movement which has developed rapidly over the past two decades as reported by Andrew (1981) and the dissatisfaction associated with the conventional measures of health which have failed to encompass the impacts of disease, impairment and the effects of health services on people's lives were the initiators lead to the development of the SIDD. The development of this measure was also influenced by the term 'quality of life' which has rapidly emerged in health services and is being incorporated in public policy as well as in prioritizing use of resources as reported by Elinson (1979). Three perspectives were adopted to construct SIDD. These three perspectives were adapted from the Wolinsky and Wolinsky (1981) model of health status which focuses on three major aspects of an individual's health status; the physical, the social and the psychological. The physical aspect is measured by the physician, the social from a societal perspective in terms of tasks and performances, while the psychological is measured from the individuals self esteem and satisfaction.

The SIDD was developed in a way that it covers both the socio-dental model of dental disease and health behaviour and it reflects that if WHO goals for health are to be achieved then social and psychological measures of impact from dental disease should be included into the assessment of dental care needs and evaluation of dental care systems.

This measure of dental impact represents the first attempt to develop social indicators of oral health status as a supplement to clinical indicators.

The qualitative interviews were conducted to develop a measure of the social and psychological impact of dental diseases based on five categories of impact:

- Eating restrictions.
- Communication restrictions.
- Pain.
- Discomfort.
- Aesthetic /self-image dissatisfaction.

Questions were constructed for each category and the score was constructed from the responses to the questions as formulated by Cushing (1986).

The indicator was tested on a large randomly selected sample. A total impact score was then derived by adding the number of categories for each individual. Two impact score were used one including discomfort, and one excluding it to check for what difference it will create in the score.

The impact categories were found to be relatively independent with two exceptions. There was a statistically significant ($P<0.02$) though weak positive correlation between eating problems and discomfort, for both genders as well as between dissatisfaction with dental appearance and restrictions of communications.

All measures of impacts related to some aspects of clinical dental caries as reported by Cushing (1986). Missing teeth were associated with eating problems and aesthetics. Pain, discomfort, communication problems and dissatisfaction with aesthetics was related to dental decay (Cushing, 1986).

Being used as an indicator of oral health status it exposed a fairly high level of dental ill health in the largely randomly selected sample of industrial workers in the North of England, but severity was not assessed. The traditional measure DMFT was not a good discriminator of the presence or absence of dental problems as reported in the results (Cushing, 1986).

2.9.3.2 SUBJECTIVE DENTAL HEALTH INDEX (RAND HEALTH STUDY)

Dimensions measured	No. of questions	Example of Questions	Response Format
Pain,worry,conversation	3	How much pain have your gums and teeth caused you?	4 categories: "not at all" to" a great deal"

(Source: Inglehart and Bagramian, 2002)

The Rand Health Insurance study (HIS) was one of the first studies to include subjective oral health indicators. The (HIS) is one of the most notable advances in the 1980's in general health status measurement developed by Ware et al. (1990). This study followed the definition proposed by the WHO and included the three dimensions identified for measurement; physical, mental and social but general health perception was also added to the study to reflect all health dimensions and to contain subjective information about health (Ware et al., 1990).

The study was basically a large scale social experiment which was designed to study the effects of health insurance on the use of health services, health status and attitudes towards care. Self-reported measures of physical, mental and social health and general health perceptions were developed following extensive literature search and evaluated. Ware et al. (1980) suggested that the three health dimensions physical, mental and social are unique, but must interrelate to be considered parts of the same health concept. When tested on a model of health status any change in any one of the components may cause changes in the other and that component both affect directly and indirectly each other.

However, it was interesting to note from the study that the relationship between oral health and broader constructs of health were never systematically explored, as generally oral health status is assessed independently, without recognizing it to be a contributor or an integral part of overall health (Dolan et al., 1991).

The index is a self-reporting measurement scale consisting of three items, making it feasible to use in a clinical setting. However, the participants were asked three questions about the adverse effects of dental disease, as the items focus only on the negative impacts

of dental health. The response range from “not at all” to “a great deal “for pain and worry questions to “none of the time” to “most of the time” about conversion avoidance question. Gooch et al. (1989) raised a concern about the validity of the measure that it is unlikely that the three items will comprehensively assess the psychological and social impact of dental disease; however, the question does address major consequences of dental disease pain, distress, worry or concern and educed social interactions.

Dolan et al. (1991) reported that the briefness of the measure and simple scoring system because the index is not weighted makes it a potential cost effective method of epidemiological data collection, as well as a tool for evaluating the effectiveness of oral health interventions and for providing data for dental health policy making.

2.9.3.3 THE DENTAL IMPACT PROFILE (DIP)

Dimensions measured	No. of questions	Example of Questions	Response Format
Appearance, eating, speech, confidence, happiness social life, relationships	25	Do you think your teeth or Denture have good effect (positive), a bad effect (negative), or no effects on your feeling comfortable	3 categories: good effect, bad effect, no effect

(Source: Inglehart and Bagramian, 2002)

The Dental Impact Profile (DIP) was developed on the concept of oral health related quality of life being equated to how much do teeth and the mouth matters in peoples' lives (Strauss and Hunt, 1990). The Dental Impact Profile was constructed to indicate how life quality has been affected, detracted from or enhanced by oral health and oral structures (Strauss, 1997). The Dental Impact profile introduced the concept that teeth and dentures have measurable positive and negative life impacts and allows for the study of health values and cultural/ethnic influences. The Dental Impact Profile examines both the good and bad effects of the teeth to allow scientists to appreciate the balance of the factors that affect how persons perceive their dentition. The measure is based upon health beliefs and values as subjectively expressed (Strauss, 1997).

The instrument was developed utilising qualitative interviews with dentists, social scientists and consumers. The original list of thirty seven items was pre-tested among elderly and college age respondents and was revised to twenty five items (Strauss and Hunt, 1993). Bowling (1998) has raised concerns about its validity as its development primarily focussed on older people, and its content validity for use among younger age groups given has been questioned in the case of measuring health related quality of life, that priorities vary among young and older people. The indicator focuses only on the effects of teeth and dentures on life quality but it does not measure the disability or dysfunction related to dental conditions (Strauss, 1997).

The indicator can be used either by being self-administered or in interview format. The 25-item instrument has four subscales, an eating subscale (eating, chewing and biting, enjoyment of eating, food choice, tasting), a healthy/well-being subscale (feeling comfortable, enjoyment of life, general happiness, general health, appetite, weight, living a long life), a social relationship subscale (facial appearance to other people, facial appearance to self, smiling and laughing, moods, speech, breath, confidence around others, attendance at activities, success at work), and romance subscale (social life, romantic relationships, having sex appeal, kissing). As derived subsequently from factor analysis (Strauss, 1997). Although these subscales have been defined, most of the use of instruments has been based on the total scores, not on subscales. Each item is scored on a three point scale indicating a “bad effect”, “no effect” or a “good effect”. That is why it captures both the negative and positive impacts of oral health. Scores expressed as percentages can be computed for each of the subscales and for the complete Dental Impact Profile. Impact scores are calculated as the proportion of positive plus negative responses among all items answered in the scale or subscale. The percentage of separate positive or negative effects may be calculated (Strauss, 1997).

The indicator has been tested in a number of studies, two pilot studies and a large population study involving a sample of 818 dentate and 200 edentulous subjects which were randomly selected from the parent study sample of more than 4000 subjects aged 65+ living in five counties in North Carolina USA. The content validity was considered in the qualitative and pre-test phases of scale development. The format and content of the scale were judged to be satisfactory by interviewers and subjects (Strauss, 1997). The ease with which subjects understood and used this scale offers some evidence of its face validity.

There is some evidence regarding the construct validity of the measure as in a population based study African Americans reported more negative and less positive impacts than did dentate Caucasians (Strauss, 1997) and medical literature does indicate poorer oral health among ethnic minorities (Locker, 1992) this can be evidence for the construct validity of the measure. However, it was interesting to note that edentulous African Americans reported fewer impacts than dentate African Americans, which raises some concerns about its construct validity. Discriminate ability was apparent in the large and consistent racial differences in the scores. The relationship of the indicator score to other clinical measures or socio-demographic factors has not been reported (Strauss, 1997).

Test-retest reliability has not been reported for the measure. The Cronbach's alpha was utilised to assess the internal consistency. A high degree of internal consistency ranging from 0.68 – 0.86 for the subscales and 0.93 for the overall scale was reported in two pilot studies involving older people (over 60 +). In a large population based study the Cronbach's alpha coefficient was reported to be 0.8, indicating good internal consistency.

As it focuses on an older population there is limited evidence of its reliability and validity for use in the general population. Strauss (1997) has argued that more testing of the indicators reliability and validity is required, especially to investigate its construct validity and how it relates to clinical oral health status. However, Strauss (1997) has reported some weakness of the measure: it is best administered by an interviewer, subscales developed have not been widely used and it does not measure the disability or dysfunction related to dental conditions.

2.9.3.4 THE GERIATRIC ORAL HEALTH ASSESSMENT INDEX (GOHAI)

Dimension measured	No. of questions	Example Of question	Response Format
Chewing, eating, social contacts, appearance, pain, worry, self-consciousness	12	How often did you limit the kinds or amounts of food you eat because of problems with your teeth or denture?	6 categories: "always" to "never"

(Source: Inglehart and Bagramian, 2002)

The Geriatric Oral Health Assessment Index (GOHAI) is the first step in developing a multi-item self-reported measure of oral health based on a functional definition of health (Atchison et al., 1990). It was developed in an attempt to estimate the degree of psychosocial impacts associated with oral diseases in older people. Atchison et al. (1990) have discussed that the development of the GOHAI was guided by several underlying assumptions: first, oral health can be measured using patient self-reports; second, levels of oral health vary among patients, and this variation can be demonstrated using a self-reported measure; third, and finally, predictors of oral health self-reports can be identified. The instrument was developed a literature review, reviewing existing questionnaires dealing with oral functions and by consulting health professionals and through open ended questioning of older people attending a senior centre.

The pilot GOHAI which consisted of 36 items was tested on a convenience sample of 87 older people and the final instrument was reduced to 12 items which contains both positive and negative items from being tested on a sample of 1911 Medicare recipients at least 65 years of age. Items for the final version were selected following analysis of frequency distribution and the effects of items for internal consistency and the initial testing of the instrument was conducted on 1755 Medicare participants (Atchison et al., 1990). As only one factor emerged from the principal components factor analysis, therefore GOHAI was considered a single construct, and no subscales were developed. Items were selected to reflect problems affecting older people in three dimensions: (1) Physical function, including eating, speech and sallow (2) psychosocial function, including worry or concern about oral health, self-image, self- consciousness about oral health, and avoidance of social contacts because of oral problems, and 93) pain or discomfort. It was one of the first measures to consider the positive aspects of the oral health related quality of life. The three items had positive dimensions: ability to swallow comfortably, how often were you pleased or happy with the looks of your teeth and gums, or dentures? and being free of discomfort. A six point Likert scale ranging from always (5) to never (0) is used for each item although most researchers have chosen five categories, one used just three categories (always, sometimes, never) (Atchison, 1997). Before calculating the final scores, the response to nine items (the negative impacts of oral health) are reversed. This means that those who respond to “never” score 5, thus allowing a final high score for the GOHAI to represent more positive oral health (Atchison, 1997). The GOHAI score is determined by summing up the final score of each of the 12 items. The scores ranged from 0 to 60.

However, as the index is not weighted, the measure lacks an insight into the severity of events or problems.

The properties of the measure were evaluated for reliability and validity using a sample of 1755 older people of whom 714 completed a clinical examination (Atchison and Dolan, 1990). The construct validity was assessed as proposed by investigators in the Rand Health Insurance Experiment (Brook et al., 1979) by association between index scores and socio-demographic factors, clinical measures or proxy clinical oral health measures (perceived need for treatment and denture status). Associations of the GOHAI with a single item rating of dental health and with clinical and socio-demographics supported the construct validity of the index (Atchison and Dolan, 1990). The bivariate analysis using chi-square statistics explored the relationship of high (5760), moderately high (51-56) and low (<50) impact scores to socio-demographic variables (age, gender, race, marital status, education, income). Respondents, who were white, well educated, and with a higher annual household income had higher GOHAI scores. Low GOHAI scores were reported for a greater proportion of those who claimed they were in need of dental treatment or for removable denture wearers.

The GOHAI demonstrated a high level of internal consistency and reliability as measured by Cronbach's alpha of 0.79. Calabrese et al. (1999) have also reported good test-retest reliability for the measure.

Several studies have utilised the GOHAI instrument and their findings have supported the validity of the measure (Atchison, 1997). The sensitivity of GOHAI to dental treatment was evaluated using data from a community-based oral health promotion project (Dolan et al., 1997). The mean change in GOHAI scores increased 2.3 points over a baseline score of 52.3 (SD=9.0). Findings suggested that the GOHAI is sensitive to the provision of dental care, as an improvement in GOHAI scores was observed following treatment; additional research is needed to understand the impact of various dental services on the individual items of the GOHAI as well as the overall index score (Dolan et al., 1997). Calabrese et al. (1996) compared the mean GOHAI score and assessment made by the dentist to that of a physician and reported good test-retest reliability. The validity of GOHAI was investigated by administering it to an all ages, low income sample of Hispanic and African Americans.

The results confirmed that GOHAI was valid when used in younger and ethnically diverse samples (Atchison, 1997; Atchison et al., 1998).

As the GOHAI has been utilized in a variety of studies and it provides summaries of people's self-reported oral function problems. The GOHAI has been tested on a variety of samples of subjects, older and younger, and on diverse samples of different ethnic backgrounds. Reliability has been reported in all samples tested. Therefore the developers of GOHAI suggested that it be renamed as the General Oral Health Assessment Index. However, as it was originally developed for assessing the impact of oral health among older people, thus its item content has questionable validity for younger people who may have different views as why oral health is important to them. So the question remains of how perceptions of health change as people age (Atchison, 1997).

In summary GOHAI has been used to validate across a number of studies Oral pain (Lamyet al., 1999), denture dislodgements (Mojon et al., 1999) and xerostomia influence masticatory difficulties (Brownie, 2006). GOHAI has been shown to be sensitive to the provision of dental care (Dolan, 1997) and more appropriate when considering functional and psychosocial impacts, and better able to detect changes within a subject than OHIP-14 (Locker et al., 2001).

2.9.3.5 THE ORAL HEALTH IMPACT PROFILE (OHIP)

Dimension measured	No. of questions	Example Of question	Response format
Function, pain, physical disability, psychological disability, social disability, handicap	49	How you had difficulty chewing foods because of problems with your teeth, mouth, or dentures?	5 categories: "very often" to "never"

(Source: Inglehart and Bagramian, 2002)

The Oral Health Impact Profile (OHIP) was developed in an attempt to measure the burden of oral health (Slade and Spencer, 1994). It is one of the most used measures of oral health related quality of life and is considered to be one of the most sophisticated instruments (Locker, 1995; Slade, 1997). The OHIP was designed to measure the dysfunction,

discomfort and disability attributed to oral conditions among older adults and elderly populations (Slade and Spencer, 1994). The OHIP does not measure any positive aspects of oral health as all the impacts in the instrument are conceptualized as adverse outcomes (Slade, 1997).

The conceptual model of oral health proposed by Locker and adapted from the ICIDH model of the WHO which attempts to capture all possible functional and psycho-social outcomes of oral disorders was used to define seven conceptual dimensions of impact: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The statements about impacts were generated by interviewing using open ended questions with a convenience sample of 64 dental patients. Interviews yielded a total of 535 statements which were then reduced to 46 unique statements selected to be representative of the complete series (Slade and Spencer, 1994). Three statements about handicap from an existing inventory (Hunt et al., 1986) were added. The instrument has a weighting system for each impact which was generated by the Thurstone's method of paired comparisons (Edward, 1957) by using a sample of 328 subjects drawn from community groups, dental practitioners and students. The moderate consensus among the judges was reported.

OHIP is a self-reported measurement scale consisting of 49 items. The instrument can be used in face to face or telephone interviews and it takes 17 minutes each to administer, in addition to a self-completed questionnaire format. OHIP-49 is scored on a five point Lickert scale. Response categories for the five point scale are: "very often", "fairly often", "occasionally", "hardly ever", and "never". For data entry responses they are coded 0 (never) to 4 (very often). The code is then multiplied by the weight and summed with each domain. Overall OHIP-49 scores can be computed in two ways. The simplest way is to count, for each subject, the number of impacts reported at the threshold level for e.g. fairy often or very often. The second method of computing an overall OHIP-49 score is to standardize subscale scores by subtracting the mean subscale value from each individual's subscale score and dividing the result by the sample standard deviation for that subscale, creating seven "Z scores" and then by summing up those standardized scores for each respondent (Slade and Spencer, 1994). Slade (1996) has argued that although the resulting standardized score has a better distribution for parametric statistical procedures but this

method requires more computing which makes this method less appealing than the simpler count method of impacts.

The reliability of the instrument is methodologically important and it encompasses both the internal consistency of individual's questions in detecting social impact and stability (across time) of the instrument. The OHIP-49 demonstrated good or excellent reliability when tested among a random sample of 122 people aged 60+ years in Adelaide, Australia (Slade and Spencer, 1994). The same level of reliability was reported when it was tested in the USA, Australia and Canada (Slade et al., 1996). Higher OHIP-49 scores were reported among socially and economically disadvantaged groups as well as among people who have infrequent or problem motivated dental visits (Slade and Spencer 1994; Slade et al., 1996; Hunt et al., 1995). Higher OHIP-49 scores have also been reported among people who have poorer clinical status as indicated by more missing teeth, more retained root fragments, the number of teeth with untreated decay, and among patients with deeper periodontal pockets and more periodontal recession (Locker and Slade, 1994; Hunt et al., 1995; Slade, 1996). These findings reflect the construct validity of the instrument. Slade and Spencer (1994) have reported that the OHIP-49 scores were associated with the perceived need for a dental visit and with satisfaction with oral health which supports the criterion validity of the measure. Locker and Slade (1993) have reported that OHIP-49 scores have shown to be associated with indices of self-reported chewing problems and self-reported oral pain which supports the convergent validity of the measure. The instrument also indicated its ability to differentiate between groups of different oral health behaviour practices as locker and Slade (1993) reported a marked difference in OHIP-49 scores among both edentulous and dentate people who did not make regular visits for dental care. The OHIP has shown poor internal consistency for the handicap domain, Cronbach's alpha 0.37 as compared for other domains, Cronbach's alpha 0.73-0.83 which is good (Slade and Spencer, 1994). The test and retest reliability of the handicap domain is also very low 0.08 as compared to four other domains 0.42-0.77 as reported by Slade and Spencer (1994). Slade (1998) has reported that OHIP-49 has shown good stability in a longitudinal study.

Locker and Jokovic (1996) reported that OHIP-49 was able to identify subgroups of individuals whose clinical conditions impacted significantly on daily life and who would probably benefit most from the treatment. Coates et al. (1996) reported higher OHIP-49

scores among dental patients with HIV infections, demonstrating its ability in relation to certain oral medical conditions. Murray et al. (1996) reported its ability to demonstrate variations in the impact of oral health on the quality of life between craniofacial patients and general population provides an evidence for its use in a clinical setting.

McGrath and Bedi (1999) raised concerns about its content validity and its appropriateness for use among the general population who are healthy as it was developed by taking into account the opinions of older people and a dentally sick population, they have further discussed that this approach has led to the fact that all items in the OHIP-49 are conceptualized as adverse outcomes, therefore the instrument only measures negative impacts.

A short form of OHIP, OHIP-14 has also been developed from analysis of South Australian data (Salde, 1997). The 14 items were derived from the original OHIP-49 by utilising further internal reliability, factor and regression analysis. The validity of the measure was evaluated by assessing associations with socio-demographic and clinical oral status variables (Slade, 1997). The OHIP-14 accounted for 94% of variance in the OHIP 49 and had high reliability (alpha=0.88) (Slade, 1997). The OHIP-14 contains questions from each of the seven domains of the OHIP-49 and has a good distribution of prevalence for individual questions suggesting that the instrument should be useful for quantifying levels of impact on well-being in settings where only a limited number of questions can be administered (Slade, 1997). Summary scores based on the OHIP-14 have displayed the same pattern of variation among socio-demographic groups that was observed using the OHIP-49, both OHIP-14 and OHIP-49 resulted in similar multivariate models relating oral status and socio-demographic variables to social impact (Slade, 1997).

There is limited evidence that OHIP-14 can be used as an outcome measure. A subset of OHIP items derived using the impact method has been developed for use as an outcome measure of tooth replacement procedure, (Allen and Locker, 2002) however, it has been suggested that it detects more change and may be better as an outcome measure in clinical trials or evaluation studies that require a shorter instrument but it may not be useful in clinical practices, as it fails to predict which subjects report improved oral health and which do not. Robinson et al. (2003) reported that OHIP-14 correlated more closely to the presence of a dental problem, described pain and self-reported oral health status however;

they also described the limitations of OHIP-14 that it is more suitable for comparing groups and have suggested its usage for questionnaire based research. However, Locker (1995) reported that although OHIP appears to be a good measure, it is only weakly associated with clinical indicators of common oral problems such as missing teeth, dental decay and periodontal disease. Collesano et al. (2005) have reported a reasonable degree of cross-cultural consistency for OHIP.

In summary OHIP-49 is widely used in clinical research. The 49-item version (OHIP-49) is the most comprehensive questionnaire to assess OHQoL and able to measure patients' problems and symptoms (John et al., 2002).

2.9.3.6 THE SUBJECTIVE ORAL HEALTH STATUS INDICATORS (SOHSI)

Dimension measured	No. of questions	Example Of question	Response format
Chewing, speaking, symptoms, eating, communication, social relations	42	During the last year, how often have (dental problems) caused you to have difficulty sleeping?	Various , depending on question format

(Source: Inglehart and Bagramian, 2002)

SOSHI was developed in Canada as a measure to describe the functional, social and psychological outcomes of oral disorders and conditions. It was intended to be used in oral health surveys of older adults in order to supplement the clinical measures routinely employed in such surveys (Locker, 1997). Its development was based on an adaptation of the WHO model of disease-impairment-disability-handicap for oral disease as Locker (1988) has discussed that this model provides a theoretical basis for the empirical exploration of the links between different dimensions of health. This indicator facilitates the exploration of the links between oral disease and their outcomes in terms of health and well-being (Locker, 1997). The items selected for inclusion in the measure were adapted in an ad hoc fashion by utilising other indices of functional, social and psychological impacts.

The indicator, which is comprised of four indexes and one scale were developed in an ad hoc fashion over a series of studies of an older population. In initial formulation, the battery consisted of an index of chewing capacity derived from the early work of Leake (1994), an oral and facial pain index, an index of other oral symptoms (Locker and Grushka, 1987) and a psychosocial impact scale partially based on questions measuring the effects of oral conditions on eating and social relationships used in the Rand Health Insurance Experiment (Dolan et al., 1991). These were used in the baseline phase of the Ontario study of the Oral Health of Older Adults (OSOHOA) (Locker, 1992). The present measure has emerged from the repeated administration of the OSOHOA. The current indicator is composed of a series of indices, it is a battery. The battery is comprised of eight subscales, a six item index of chewing capacity (Leake, 1994), a three item index of the ability to speak clearly, a nine item index of oral and facial pain (Locker and Grushka, 1987) and a ten item index of other oral symptoms. The scale of the social and psychological impact of oral disorders is assessed by four subscales: a three item subscale of problems with eating, a four item subscale concerned with problems in communication/social relations, a six item subscale of other limitations in daily activities and a two item subscale of worry and concern about oral health (Locker, 1992).

The first four subscales are scored by yes or no answers; the others are scored on a five point Lickert Scale with responses coded: never (1) to all time (5). The scoring is done in the following way: for the first subscale "ability to chew", the numbers of 'no' responses are added up; for the subclass 2-4, "ability to speak", "oral and facial pain symptoms" and "other oral symptoms" subscales, the number of 'yes' responses are added up. For the others "activities of daily impact " and "worry/concern" the count number of 'all the time', 'very often', 'fairly often', 'sometimes' or a sum of all response codes (all the time (5), never (1)) can be used, however, the index is not weighted.

The index has been tested in a number of studies in Canada and the UK (Locker, 1992; locker and Miller, 1994; Richards and Scourfield, 1996; Tickle et al., 1997). Locker and Miller (1994) have reported a good construct and criterion validity of the measure by reporting the correlation between the eight measures and three global self-reported indicators: self-rating of oral health, self-perceived need for dental treatment and dissatisfaction with oral health. Moreover, significant differences were observed in five of the indicators according to dental status (edentulous, dentate with dentures, dentate without

dentures) (Locker 1992; Locker and Miller, 1994; Richards and Scourfield, 1996; Tickle et al., 1997). Also theoretical propositions derived from the conceptual model were also confirmed using these measures (Locker and Miller, 1994). Tickle et al. (1997) also reported that pain and chewing problems are important significant predictors of psychosocial impact which supports the instrument validity. Tickle and Worthington (1997) have reported variations in SOSHI scores in relation to self-reported dental attendance patterns which demonstrate the instrument's ability to differentiate between groups of different oral health behaviours patterns. Concurrent validity was assessed by correlating subscales score to overall OHIP scores (Locker, 1997). The correlation between scores on the index of chewing capacity and the overall OHIP score was 0.56, and the correlation between a combined psychosocial impact sore and the overall OHIP score was 0.68. Locker (1997) used longitudinal data from the OSOHOA to assess the sensitivity of the indicators to change over time and reported a significant association between change scores (obtained by subtracting follow up from baseline scores) and subjects' global assessments of change in their oral health status. Locker and Miller (1994) also reported a high internal consistency of the indicator, the Cronbach's alpha values ranged from 0.70 to 0.87. Tickle et al. (1997) has also reported its high internal reliability with values ranging from 0.80-0.90 in a study conducted in the UK. Locker and Miller (1994) have reported its efficiency by numbers of item non response and found that non response to questions was less than 5% for six indicators and just over 7% for the remaining two. Good test-retest reliability has also been reported for the measure with values ranging from 0.75-0.90 for six scales and 0.61-0.67 for the other two. Tickle et al. (1997) reported in the UK study Kappa values ranging from 0.40 for the activities of daily living sub scale and difficulty in speaking sub scale to 0.90 of the difficulty in chewing subscale.

Locker (1997) has suggested that as the instrument is based on a coherent conceptual framework, so it is useful in descriptive surveys and more theoretically oriented work which explores the links between distinct dimensions of health, rather than an outcome measure for evaluative studies or clinical trials. Its main value appears to be describing and monitoring the self-perceived oral health status of adult populations (Locker, 1997). The items focus only on the negative impacts of oral health and the index is rather lengthy to administer in practice as reported by Locker (1997). McGrath and Bedi (1999) have raised concerns about its content validity, as the items were selected for inclusion was done in an 'ad hoc' fashion utilising other indices of functional, social and psychological impacts, it

appears that it may be measuring what people 'ought' to feel rather than what they actually feel. Primarily the index was developed for use among older people but Locker and Miller (1994) have carried out a comprehensive evaluation of the performance of the SOSHI measure among a randomly selected general population sample (aged 18 years or older).

Despite being developed in an ad hoc fashion the measure is regarded as a preliminary measure of the social and psychological impact of oral health.

2.9.3.7 THE ORAL HEALTH RELATED QUALITY OF LIFE MEASURE (OHQOL)

Dimension measured	No. of questions	Example Of question	Response format
Daily activities, social activities, conversion	3	Have problems with your teeth or gums affected your daily activities such as work or hobbies?	6 categories: "all of the time" to "none of the time"

(Source: Inglehart and Bagramian, 2002)

The OHQoL measure is a brief global assessment of the impact of oral conditions on individuals functioning and well-being (Kressin, 1997). The measure was developed by utilising pools of items from already existing instruments which assess various impacts of oral health on the quality of life (Kressin et al., 1996). The measure is a brief global assessment of the impact of oral conditions on individuals' functioning and well-being. The pool of items consisted of three items from the Dental Health Index, relating to problems with teeth or gums affecting daily activities, social activities an avoidance of conversation (Dolan et al., 1991). Two items were from the Nutritional screening Initiative relating to eating problems (Nutritional Screening Initiative, 1991), two items on oral discomfort and one item on pain. Three items were selected following factor analysis using Promax rotation. A three factor solution was obtained which accounted for 49% of the total variance because, the first factor included the items related to the impact of oral conditions on daily functioning this factor was labelled the OHQoL, the second factor was labelled oral discomfort, and the third was labelled eating problems (Kressin et al., 1996).

Factor correlations were negative and relatively low, ranging from -0.24 to 0.02.These findings suggest that OHQoL is negatively related to oral discomfort and that is largely independent of eating problems (Kressin et al., 1996). Kressin (1997) reported that the theoretical concept of the item pool selection was based on the concept of health related quality of life as the impact of health on well-being and daily function in everyday life.

The OHQoL measure is composed of three questions which are concerned with the possible effects of oral disease: Have problems with your teeth or gums: 1) affected your daily activities such as work or hobbies? 2) Affected your social activities such as with family, friends, and co-workers? 3) Caused you to avoid conversations with people because of how you looked?

Each question is scored on a six point Lickert scale, responses ranging from 'none of the time' (1) to 'all of the time' (6). Summing up the response to individual items can generate a total impact score. The distribution of response indicates that the measure is highly skewed towards health with the vast majority (over 90%) claiming that their oral health had no impact on their quality of life (Kressin, 1996; Kressin et al., 1996). The measure does not incorporate a weighting system.

OHQoL has been tested mainly on older populations, for example, on a large sample of 2,280 men whose mean age was 67.3 (Kressin et al., 1996). The measure has been tested on a group of 957 male veterans and subsequently amongst a group of 911 veteran women (Kressin, 1996, Kressin, 1997).

The internal consistency reliability of the OHQoL scale was also evaluated; its Cronbach's alpha was 0.83, suggesting strong associations among the items (Kressin et al., 1996). These results indicate that respondents with better oral health related quality of life had fewer eating problems and less discomfort; they reported less dental pain and were less likely to have sought treatment for problems during the previous three months (Kressin et al. 1996). Correlations between oral health related quality of life and general life satisfaction and self –rated health were small, but in the expected directions reported by Kressin et al. (1996) which indicated the construct validity of the measure. The small but statistically significant correlation between OHQoL and general life satisfaction suggests that social well-being is related to perceptions of the impacts of oral health on quality of

life, further findings in the study reported negative correlations between general life satisfaction and both oral discomfort and pain. Higher scores were observed among higher socioeconomic groups upholding the indicators construct validity (Kressin, 1996).

There is no evidence about test-retest reliability of the measure. The OHQoL measure is a brief three item measure making it ideal for inclusion in population surveys, but its briefness makes it weak to assess much detail about specific impacts of oral disease on quality of life (Kressin, 1997). Overall the instrument exhibits good psychometric properties, including good internal consistency, reliability and associations in the expected directions with external criteria (Kressin, 1997). However, McGrath and Bedi (1999) have raised concern about the approach to item selection, since the item pools relate to normative assessment of oral health related quality of life and in that way it raises concerns about the content validity of the measure. However, further research is needed to make a clear understanding whether it is appropriate to use it as an indicator of perceived need for dental care and as a predictor of dental utilization, and whether it can be used as an assessment of treatment outcomes as suggested by Kressin (1997).

2.9.3.8 THE DENTAL IMPACT ON DAILY LIVING (DIDL)

Dimension measured	No. of questions	Example Of question	Response format
Comfort, appearance, pain, daily activities, eating	36	How satisfied have you been on the whole, with your teeth in the last 3 months?	Various depending on question format

(Source: Inglehart and Bagramian, 2002)

The DIDL is a socio-dental measure and was developed by conducting open ended interviews, literature review and items in the existing measure "Social Impact of Dental Disease" (Leao and Sheiham, 1995; Cushing et al., 1986). After conducting inter-item correlation and item total correlation (Streiner and Norman, 1991) numbers of items were reduced to 36. In addition as a result of factor analysis a fifth dimension was added to the instrument, the five dimensions are: Comfort, related to complaints such as bleeding gums and food packing; Appearance, consisting of self-image; Pain; Performance, the ability to

carry out daily activities and to interact with people; and eating restrictions, relating to difficulties in biting and chewing.

It consists of 36 items for the basic questionnaire (for those subjects without a removable partial dental prosthesis), 42 or those with partial dentures, 45 for those wearing full dentures (upper and lower) and 47 for those wearing both partial and full dentures. The measure is administered in an interview format but its length may make it time consuming to use in clinical settings or epidemiological surveys. The response format for each item ranges from (+1) very satisfied, satisfied; (0) more or less satisfied; and (-1) unsatisfied, very unsatisfied. The items within each dimension are then summed up and divided by the number of dimension items. Weights are attributed on a scale of 0-10 for each dimension and respondents are asked to record on the scale the relative importance they attribute to each dimension (in relation to others) but after a correlation between three different versions of the measure Leao and Sheiham (1997) reported that the performance of the measure is not affected whether the instrument is weighted or not. They reported a high correlation between un-weighted and weighted item scores.

The instrument was used in the cross sectional study of a Brazilian sample of 662 subjects aged 35-44 of two different social classes, determined by seven economic indicators. The face validity of the measure has been reported satisfactory as respondents interviewed understood the items. The content validity was established through open interviews and literature review (Leao and Sheiham, 1997). The construct validity of the measure was evaluated by using two tests. First the relationship between DIDL scores and clinical oral health status: number of decayed, missing, filled teeth, overall caries experience, functional teeth (aggregate of filled and sound), and health scores (arbitrary weight to the status of the tooth) and periodontal status was assessed (Leao and Sheiham, 1996). Results showed a weak but significant association between oral health status and DIDL scores. However, there was a significant association between DMFT scores (caries experience) and DIDL scores (total and domains). The health and number of functional teeth were positively related to all domains except comfort. The number of decayed teeth and a number of missing teeth were negatively associated with total scores and all domain scores except for comfort. Number of fillings were related to two domain scores: comfort (negatively) and performance (positively) although not to the total score. Periodontal health was also associated with DIDL scores as bleeding and periodontal pockets were

associated with total and all domain scores except for pain. Calculus deposition was associated with total and domain scores except for eating and pain (Leao and Seiham, 1996). The construct validity was also reported in a complementary study where respondents were asked to weight all dimensions and also all items in the questionnaire. The orders of the items were assessed by the Wilcoxon signed rank test and were compared to weights attributed to the domains and they were found similar (Leao, 1993).

Laeo and Sheiham (1995) have reported socio-demographic variations in DIDL scores in relation to different social classes and gender. The analysis revealed that for different social classes there was a significant difference in total and domain scores except comfort, which further supports the construct validity of the measure. Gender variations were not apparent except in relation to comfort and pain domain scores (Leao, 1993). The internal reliability (Cronbach'salpa) of the items was 0.85 and for the weighting scale it was 0.59. Over 10% of the sample assessed test-retest reliability when they were re interviewed (Leao, 1993).

The measure offers a degree of flexibility in terms of aggregating and disaggregating data (either individual items, dimension scores or total scores). However, it is lengthy to administer and thus it raises a question about its usage in clinical setting. Concerns have been raised about its scoring system as in some items scores are scored as positive rather than neutrally for not experiencing negative influences. McGrath and Bedi (1999) have argued that as it was developed and validated in Brazil, it raises questions of cross cultural validity in terms of variations in what constitutes oral health related quality of life among different populations.

2.9.3.9 ORAL HEALTH QUALITY OF LIFE INVENTORY (OH-QOL)

Dimension measured	No. of questions	Example Of question	Response format
Oral health, nutrition, self-rated oral health, overall quality of life	56	Two-part questions: (A) How important is it for you to speak clearly? (B) How happy are you with your ability to speak clearly?	Part A: 4 categories (not at all important to very important) Part B: 4 categories (unhappy to happy)

(Source: Inglehart and Bagramian, 2002)

The Oral Health Quality of Life Inventory (OH-QoL) is a dental specific measure that assesses a person's satisfaction with his or her health and functional status, as well as the importance he or she attributes to oral health and functional status (Cornell et al., 1997). It was developed on a model of the functional and psychosocial effects of oral health and on subjective well-being (Frisch, 1994). This measure re-establishes the role of the personal or "humanistic" elements into the quality of life equation (Gerin et al., 1992; Frisch, 1994; Frisch et al., 1992). The inclusion of the subjective well-being dimensions in the assessment process was to complement traditional measures of objective functional status; self-reported symptoms and functional impacts. However it is interesting to note that the items selected are just the synthesis of the literature and expert judgement which eventually raises a question about the content validity of the measure as it fails to incorporate individuals or population's perceptions.

Initially the item consisted of 22 items but the final scale is a 15 item dental specific measure as by testing on a small sample, the remaining items were dropped because of the reasons of variability, item total correlation, internal consistency and weak associations with the total score. One of the fifteen items applies to denture wearers only (Cornell et al., 1997). The measure covers six dental specific domains: salivary function, taste, dental-facial aesthetics, oral-facial pain, speech, chewing and swallowing and global oral health. It focuses primarily on the negative impacts of oral health and predominantly on the symptoms.

The OH-QoL items are rated on two dimensions: importance and satisfaction. Importance is rated on scale coded (0) not at all important; (1) somewhat important; and (2) very important. The satisfaction responses are coded as: (-2) unhappy; (-1) somewhat unhappy (+1) somewhat happy and (+2) happy. An OH-QoL score for an item is the product of importance multiplied by satisfaction rating which yields a score that ranges from (-4) to (+4). The response format follows the format developed for the generic quality of life inventory QOLI ™ (Frisch, 1994).

The measure was administered along with the QOLI ™ and SLIT ™ to a systematic sample of 100 adults patients aged between 20 and 84 years of age scheduled for dental diagnostic screening at a dental clinic. The OH-QoL had an internal consistency of alpha= 0.84 and also correlated well with the generic quality of life inventory (QOLI) and self-

confidence in life test (SILT). This supports the criterion validity of the instrument (Frisch, 1994). In addition the OH-QoL scores were strongly correlated with scales of self-reported oral health problems: self-reported speech, swallowing and chewing problems. All correlations were significant at P<0.05 level or less. Cornell et al. (1997) have reported in a study involving 290 participants from different ethnic backgrounds, variations in OH-QoL scores in relation to ethnic background were observed Mexican Americans reported greater dissatisfaction with dental-facial aesthetics and their over-all oral health this further supports the construct validity of the measure.

Cornell et al. (1997) reported the internal consistency (Cronbach's alpha) of OHQoL of 0.84 and 0.91in a study of the small convenience sample. When the measure was translated into Spanish and tested on a population based epidemiological survey, it exhibited good internal reliability (Cronbach's alpha 0.81). There is no evidence of test-retest reliability.

The measure lacks items relating to social and psychological aspects of oral health adequately as well it primarily focuses on the negative impacts of oral health, predominantly on the symptoms.

It also lacks the individuals or population's perceptions raising concern about its content validity.

2.9.3.10 ORAL IMPACTS ON DAILY PERFORMANCES (OIDP)

Dimension measured	No. of questions	Example Of question	Response Format
Performance in eating, speaking, oral hygiene, sleeping, appearance, emotion	9	Four-part questions: (A) In the past 6 months, have (dental problems) caused you any difficulty in eating and enjoying food? (B) Have you had this difficulty on a regular/periodic basis or for a period /spell? (C) During the last 6 months, how often have you had this difficulty? (D) Using a scale from 0 to 5, which number reflects what impact the difficulty in eating and enjoying food had on your daily life?	Various, depending on question format

(Source: Inglehart and Bagramian, 2002)

The aim behind the development of Oral Impact on Daily Performances (OIDP) measure was to provide an alternative socio-dental indicator which focussed on measuring the serious impacts on the person's ability to perform daily activities (Adulyanon, 1996). Its development was also based on the theoretical World Health Organisation's international

classification of disease-impairment-disability-handicap amended for dentistry by Locker (Locker, 1988). The OIDP focuses to measure the ultimate impact of oral health such as how it affects one's physical, social and psychological performances in carrying out daily activities. Items were selected from various socio-medical and socio-dental indicators including SIDD (Cushing et al., 1986) and DIDL (Lao and Sheiham, 1995) utilising comparison tables of disability indices (McDowell and Newell, 1987). This approach was deemed to have the advantage of being short and easier to measure. However, Slade and Spencer (1994) have reported that such ultimate handicapping influences of oral health are rare. Slade et al. (1996) have further argued that this approach was reported to add to the content validity of the measure but it fails to consult within the population or even patient group so as to what constitute ultimate impacts in relation to oral health.

Initially nine items relating to physical, psychological and social performances were developed from the comparison table of disability indices (McDowell and Newell, 1987) and from various other socio-medical and socio-dental indicators. After analysis of internal consistency, and item-total score correlation, one of the performance activities, 'doing light physical activities' was considered redundant and was excluded (Adulyanon and Sheiham, 1997). The final version consists of eight items: eating and enjoying food; speaking and pronouncing clearly; cleaning teeth; sleeping and relaxing; smiling, laughing and showing teeth without embarrassment; maintaining the usual emotional state without being irritable; carrying out major work or social role and enjoying contact with people. Adulyanon and Sheiham (1997) has discussed that the questions are phrased in such a way that they only measure the negative oral impacts on daily performances.

The items are scored according to frequency and severity which was modified from the questionnaire of the National Survey of Health and Development (Medical Research Council, 1989). Frequency scores are described by the respondents according to whether the impact is "regular" (those never affected in the past six months score 0, less than once a month score 1, once or twice a week score 3, 3-4 times a week score 4, every or nearly every day score 5). Frequency of effects is also be classified as "spell" which relates to the length of time people experience impacts (if the duration is for 0 days then the score is 0, for up to 5 days in total the score is 1, for up to 15 days in total the score is 2, for up to 30 days in total the score is 3, for up to 3 months in total the score is 4 and for up to over 3 months in total the score is 5) (Adulyanon and Sheiham, 1997). For example a person who

twice experienced impacts on eating during the past six months for five days in total should receive a score 2 according to period/spell basis, rather than the score of 1 according to regular/periodic basis. The perceived severity of impacts in the OIDP is scored from 0 to 5 representing 5 'very severe' to 0 representing 'none'. A total OIDP score can be calculated by multiplying the frequency of the impact score with severity score. The sum is then divided by the maximum possible score (200) and multiplying by 100 gives the percentage score (Adulyanon and Sheiham, 1997).

The questionnaire was tested on a random cluster sample of 501 villagers in Thailand aged between 35-44 years of age. The villagers were examined clinically and responded to the OIDP indicator and questions relating to self-rating of oral health. The measure exhibited content validity, although this is questionable in that field as it failed to incorporate the individual's perceptions of the study population. The construct validity was assessed by correlating score to numbers of functional teeth, decayed teeth, missing teeth, and sextants with deep periodontal pockets. Those with poorer oral conditions had higher OIDP scores as compared to lower scores exhibited by those who had better clinical oral health scores. Correlating scores to perceptions of trouble with oral health assessed the criterion validity and this was strongly correlated as reported by Adulyanon (1996). The internal consistency measured by Cronbach's alpha was 0.65; the standardised item alpha was 0.67. The test-retest reliability was good for frequency scores it ranged from 0.95-1; severity scores ranged from 0.57-1. These findings support the reliability of measure (Adulyanon and Sheiham, 1997).

OIDP was satisfactory as regards construct and criterion validity. The scores discriminated clearly between groups of relatively and those with poor oral health status as well as between people who had different perceptions of overall impacts (Adulyanon and Sheiham, 1997).

Robison et al. (2003) has reported weak face validity of OIDP because it contained contingency questions in the UK setting. However, Okullo et al. (2003) reported OIDP frequency score have acceptable psychometric properties in the context of an oral health survey among Ugandan adolescents.

In summary the OIDP provides a significant endpoint outcome scale for oral conditions within a concise, reliable and valid measurement.

2.10.3.11 ORAL HEALTH RELATED QUALITY OF LIFE – UK (OHQOL-UK)

Dimension measured	No. of questions	Example Of question	Response Format
Eating, appearances, speech, breathe odour, social life, romantic relationships, confidence, sleep, and mood.	16	What effect, if does the condition of your teeth, gums, mouth or dentures have on your appearance? How would you rate the impact of that effect on your quality of life?	Responses were scored firstly on "effect" with responses ranging from bad-to-good effect on quality of life and then respondents were asked to rate the "impacts" of each 'effect' on a scale ranging from none to extreme impact.

(Source: Inglehart and Bagramian, 2002)

The UK Oral Health Related Quality of Life instruments items were derived from the public perceptions in the UK of how oral health influences quality of life (McGrath et al., 2000). Public perceptions were obtained from a large random probability sample of adult residents across England, Wales and Scotland. This measure incorporates both positive and negative dimensions and captures individuals rating of the impact of oral health effects on quality of life (McGrath et al., 2000).

The measure was developed using open-ended interviews with a large random probability sample of UK residents (1,865) with the assistance of the Office for National Statistics. From the verbatim response the ways in which oral health affects quality of life were identified and categorised by three independent researches and coded for analysis. The 16 key areas of oral health quality of life were identified (McGrath et al., 2000). Therefore, the instruments final version contains 16 items: eating, appearances, speech, health, relax/sleep, social, romance, smile/laugh, confidence, carefree, mood, work, finance, personality, comfort and breath. The questions are phrased in a way that the instrument measures both positive and negative dimensions of oral health related quality of life (McGrath et al., 2001).

The items are scored firstly on ‘effect’ with responses ranging from bad-to-good effect on quality of life. Then the respondents are asked to rate the ‘impact’ of each ‘effect’ on a scale ranging from none-to-extreme impact, in that way incorporating an individual weighting system. Each of the item is thus scored on a scale from 1 to 9 , a ‘bad effect’ of ‘extreme impact’ scores 1, a ‘good effect’ of ‘extreme impact’ scores 9, ‘no effect’ of ‘no impact’ is given a score of 5. Summing up individual item responses generate an over-all score with possible scores ranging from 16 to 144.

This measure can be seen as a single construct of oral health related quality of life with a single outcome score as all items were moderately to highly correlated with one factor reporting correlation above 0.40 (McGrath et al., 2001). Marked variations in scores were reported in relation to self-rating of oral health status. The measure’s internal reliability as assessed by Cronbach alpha value was 0.94. No correlation was negative which shows the homogeneity of the items as well no correlation was high enough for any item. The scores of the measure were more skewed towards positive oral health related quality of life as many of the respondents claimed that their oral health status more frequently enhanced quality of life as opposed to detracting from it as reported by McGrath et al. (2001). The ability of the instrument to differentiate between people who rated their oral health differently supports the criterion validity of the instrument. The instrument showed good construct reliability as it was able to differentiate between people of different oral health status in terms of self- reported number of teeth, possessed and denture status.

The instrument has demonstrated satisfactory internal reliability, construct and criterion validity (Mc Grath et al., 2002; 2004).

2.10 ENDODONTIC AND QUALITY OF LIFE

2.10.1 INTRODUCTION

Dentistry is a young profession that emerged in the mid 19th century as a separate discipline that focussed on treatment of diseases of the teeth and their supporting tissues. Dental and oral health problems have inflicted humans throughout history (Ismail et al., 2001). Greco-Roman medicine included detail observations on the aetiology and treatment

of dental caries. Treatment for dental caries loose teeth, jaw fractures, and infections were developed during this period (Ismail et al., 2001). Until the 18th century, dental treatment was simple and was based on the extraction of teeth. With the beginning of the second industrial revolution in 1875 dentistry saw a new revolution that focussed on conserving teeth rather that extracting them. This era saw significant economic and social changes in Europe and the US. The dispersion of wealth and creation of middle class working families in the largest cities created new demands on all services and professions. The movement for restoring rather than extracting teeth started to gain momentum almost 150 years ago. Late in the 19th century dentists were faced with an increasing demand to conserve teeth from the ravages of dental caries. A demand in awareness of dental health care has seen a rise in the demands for procedures that help to retain teeth.

Despite the fact that the level of decay is in decline in some parts of the world there has been an increase in presentation of clinical problems due to erosion, attrition, abrasion and trauma which has resulted in an increased demand for fixed restorative treatment, which aims to restore aesthetics and function. Trauma and restorative procedures may lead to damage to the pulp and consequently problems related to pulp and peri-radicular tissue has also increased. When the pulp is diseased, damaged or injured, endodontic treatment is needed to maintain or restore the health of the peri-radicular tissue (Stock et al., 1995).

2.10.2 DEFINITION OF ROOT CANAL TREATMENT

"Endodontolgy is concerned with the study of the form, function and health of, injuries to and diseases of the dental pulp and peri-radicular region and the prevention and treatment of apical periodontitis, caused by infection" (European Science of Endodontology, 2006).
The technical aim of the endodontic treatment is the shaping and cleaning of the root canal system and the fillings of the canals as if to prevent coronal leakage and entomb remaining microorganisms preventing them from irritating the periapical tissues (Sundqvist et al., 1998).

Root canal treatment is a "non-surgical" approach used to treat two distinct endodontic disease (1) by extirpating vital, but irreversibly inflamed pulp to maintain existing periodical health and thus preventing periapical disease; or (2) the removal of the non-vital

or dying, infected pulp, associated with apical periodontitis to restore the periradicular tissues back to health. The overall goal of root canal treatment or endodontic therapy is therefore to prevent or treat periapical disease (European Society of Endodontology 2006).

2.10.3 HISTORICAL PERSPECTIVE

Historically as reported by Rowe (1968) the aim of the dental treatment was pain relief. Ancient root canal filling found was reported by Joseph Zias in the Journal of American Dental Association (1987). Radiographic examination of the maxillary right lateral incisor dated from the Hellenistic period (200 BC) revealed a metal wire embedded in the root canal of the tooth. Professor Zias went on to explain the probable reason for the primitive "Endodontics": "The accepted cause of tooth disease in the Mediterranean—a worm burrowing inside the tooth— may give a clue as to why this tooth was filled with a metal wire. It is possible that the wire was implanted into the tooth canal to close the passage and prevent 'toothworms' from burrowing into the tooth and causing further dental pain." (Zias, 1987). Worm-like living creature as a cause of dental disease has also been reported in China Ying Dynasty in 1400 BC (Tsao 1984). Various clinical approaches ranging from placement of arsenic to cauterization of the pulp has been reported in literature (Rowe; 1968). In all approaches the interior of the tooth was suspected as the possible origin of toothache and related to the presence of a nerve supply and inflammation. Grossman (1987) has reported that "Pierre Fauchard, the noted French dentist (1678-1761), had dispelled the 'toothworm' legend and was recommending the removal of diseased pulps as well."

Grossman (1987) has reported four eras which impacted on the development of the modern endodontic therapy:

- 1776-1826: crude treatment crude—abscessed teeth were treated with leeches or toasted fig poultices, and pulps were cauterized with red-hot wires. Root canals were being filled from apex to crown with gold foil.
- 1826-1876: saw the development and introduction of the barbed broaches, gutta-percha, rubber dam but arsenic was still used to devitalise the pulp as well as

crowns of the teeth were also being “snipped” off at the gingival level to cure toothache.

- 1876-1926 saw the development of x-ray, the introduction of the local anaesthetics and acceptance of asepsis as a part of endodontic therapy. This phase also saw the set back of endodontic therapy as theory of focal infection was widely accepted which led to advocation of extraction of the teeth?
- 1926-1976 era led to the development of the saw improvements in radiographs, anaesthetics, and procedures as well as the introduction of new methods and agents which have led to the development of the modern endodontic therapy treatment.

2.10.4 THE BASIS FOR MODERN ENDODONTIC TREATMENT

The principles of contemporary pulp and root canal treatment had been fully established now but Hall (1928) interesting findings is still deemed to hold true in the 21st century. He suggested that endodontic treatment should: never destroy a vital pulp; use surgical asepsis; use measurement to control instrument trauma; not be performed without radiographs; not enlarge the apical foramen or go beyond the cemento-dentinal junction; not pump, push, or expel septic matter through the apical foramen; not use tissue-destroying drugs in root canals; never leave a tooth unsealed; not be based on a few special cases; and never be observed for only a short time. He advocated longitudinal follow-up of the treatment which has been advocated by European Society of Endodontology (2006).

2.10.5 ENDODONTIC AND QUALITY OF LIFE

Endodontic disease adversely affects quality of life and can produce significant morbidity in afflicted patients (AAE 2010).

Follow-up clinical studies have shown that root canal treatment applying modern principles of practice can yield favourable outcome with healing rates well above 90% (Salehrabi et al., 2004). It appears that patients also sense improved quality of life and satisfaction with their decision to have endodontic treatment rather than extraction. It has been found that nonsurgical endodontic treatment is a predictable procedure with excellent

long-term prognosis when studies looked at retained teeth after endodontic treatment (Lazarski et al., 2001; Salehrabi et al., 2004).

The American Endodontic Society (2001) has discussed that by combining the expertise of outstanding endodontic care and subsequent restorative treatment we can save our patients' natural teeth with years of satisfaction and improved quality of life. High-quality endodontic and restorative procedures play an important role in obtaining the highest level of success that our patients expect and deserve (Doyle et al., 2006).

Bader & Shugars (1995) classified dental outcomes in four dimensions:

- Physical/physiological dimension: presence of pain, pathology and assessment of function.
- Psychological dimension: level of oral health, perceived aesthetics, satisfaction with oral health status, self-concept and interpersonal relations.
- Economic dimension: direct and indirect cost.
- Longevity/survival dimension: tooth loss, retreatment of the same condition or new condition as a result of treatment.

If we look at the literature concerned with endodontic treatment outcomes, mainly the physiological dimension has been addressed namely the presence or absence of disease. Clinicians and researchers both have looked at the success and outcomes as the absence of both clinical signs and symptoms and radiographic evidence of disease (Chugal et al., 2001; Sundqvist et al., 1998). European Society of Endodontology (2006) guidelines suggest that after completion of endodontic treatment clinical and radiographic follow-ups at regular intervals for a minimum observation period of one year are desirable, but longer may be required where healing is incomplete or there is a history of trauma and have suggested radiological follow-ups for up-to four years if is a there is a persisting lesion evident on radiographs' after one year of treatment.

Endodontic treatment has significantly improved quality of life of patients in a study conducted by Dugass et al., (2002) in which the researchers have used items from OHIP-49 to look at psycho social aspects of the endodontic treatment; they found that the quality

of life of patients was found to improve significantly after endodontic treatment as a result of pain relief and allowed return to normal sleep patterns.

2.10.6 ENDODONTIC TREATMENT IN NATIONAL HEALTH SERVICE IN ENGLAND & WALES

A large amount of money spent in the provision of root canal therapy which is paid for in the primary care setting by the taxpayer through the NHS and also patients paying through their own pocket privately.

A substantial amount of endodontic treatment is carried out within the GDS. In 2002-2003, 1,040,565 root fillings were placed in adults by dentists working in the GDS in England and Wales. This compares with 1,003,449 in 2001/02. In 2002/03 this cost £50,204,951 and £47,106,247 the previous year. When endodontic treatments for children and surgical endodontic are included, the total cost for endodontic treatments in 2002-2003 was £55,451,112.

However, data from the NHS Information Centre indicate that the proportion of time dentists has spent on root canals and conservation work has fallen significantly while that spent on high- tech, higher reward treatments such as bridgework and braces has risen. Between 2008 and 2009, the number of treatments involving root canal work fell by nearly 40 per cent, from 907,000 to 549,000.

Many infected teeth can be retained by root canal therapy, the alternative way of rendering patients dentally fit is to eliminate pain and remove infection by extracting the tooth. The preliminary results of the dental treatment band analysis in England from April to July 2007 demonstrate that there has been a reduction in approximately 45% of adult courses of treatment that contain a root-filling episode from 2003-04 to 2007 and an increase in extractions.

These findings have been reported after implementation of the new GDS contract in April 2006. The British Endodontic Society reported “the new contract provided dentists with a

'financial incentive to persuade a patient to have a decayed tooth extracted rather than undergo the more complex procedure of restoring it". The British Endodontic Society said the new contract provided dentists with a 'financial incentive to persuade a patient to have a decayed tooth extracted rather than undergo the more complex procedure of restoring it'. The British Endodontic Society said the new contract provided dentists with a 'financial incentive to persuade a patient to have a decayed tooth extracted rather than undergo the more complex procedure of restoring it'. However, the new proposed dental contract currently being piloted focuses on improvement in quality and healthcare outcomes. The aim is an NHS dental service that delivers high-quality, clinically appropriate preventative, routine and complex care for those who choose it (DOH, 2010) and endodontic treatment is one of the complex treatment encountered by the GDP in routine practice.

2.11 SUMMARY

During the first half of the past century, health was assessed mostly in terms of survival and morbidity. The World Health Organization definition of health generated a broader concept of health incorporating physical, mental and social dimensions. There is no consensus about how to define quality of life but it is considered to be a broader concept than health. The broader term Health Related Quality of Life (HRQol) refers to the extent to which individuals usual or expected physical, emotional and social well-being is affected by a medical condition or its treatment.

There is no universally accepted conceptual model to explain HRQoL. As we have looked at the conceptual models, they range from a simple linear model (Wilson and Cleary model) to a complex model (ICF model) that incorporates bidirectional arrows that link elements of health, functioning and disability.

The emerging concept of HRQoL and evidence based medicine had led to the new concept of the need for health as it is perceived as a relief from distress, discomfort, disability, handicap and risk of mortality and morbidity.

The concept of positive health without the perception of health as a right is empty, while the acceptance of the idea that health is right without the concept of positive health,

broadly defined is blind (Conrad, 1987). Positive health has become a question which will remain a permanent item on the agenda of human kind.

HRQoL has become an essential outcome measure in the evaluation of treatments. It helps in clinical decision making; it helps redirect the sources available to provide the best evidence based treatment available. HRQoL evaluation differs from classical toxicity ratings in two important ways. Firstly, it encompasses more functional aspects of an individual (e.g. mood, affect, social well-being) than those which have typically been attributed to treatment, and secondly, it focuses on the patient's perspective

HRQoL measures being developed should include those elements of HRQoL that (a) are sensitive to changes over time, (b) can be reliably and validly assessed, and (c) account for most of the variance in an individual's rating of his/her overall well-being. This thesis is an attempt to develop a brief patient-based outcome measure encompassing all those elements discussed above.

Indicators are needed to ensure that the service delivered is in line with patients' expectations, and that the outcomes are in line with what patients want and need. NHS dentistry accounts for nearly £3 billion of public expenditure (including the charges that patients pay) there is a desired need to measure the quality of work and the clinical outcomes as a result of interventions being provided by dentists.

A number of generic HRQoL have been developed. The SF 36 is the most commonly used HRQoL measures. It was developed as a short form measure of functioning and well-being in the MOS. The NHP was developed to reflect lay rather than professional's perceptions of health. The SIP was developed as a measure of sickness in relation to impact on behaviour. The QWB scale, HUI and EQ-5D are preference based measures designed to summarize HRQoL in a single number ranging from 0 to 1.

Condition-specific instruments are the most commonly used specific measures to assess OHRQoL. There are several oral disease-specific instruments available but each has a unique profile. As more and more adults are retaining their natural teeth Adult Dental Health Survey 2009 has reported the proportion of adults in England who were edentate (no natural teeth) has fallen by 22 percentage points from 28 per cent in 1978 to 6 per cent

in 2009. It is evident from comparing previous Adult Dental Health Surveys the likelihood of retaining not just some teeth, but a considerable number of healthy teeth through the whole of a long life, is now very high. However, there will be desired need for more and more complex treatment as reported by Professor Steele et al. (2009) in this survey. Endodontic is one of the complex treatments which has only been accessed by clinical approach there is a need to balance this approach with patient-centred approach and there is a need to develop patient outcome measure for endodontic treatment

CHAPTER 3 AIM, OBJECTIVES AND NULL HYPOTHESIS

3.1 AIM

The aim of this project is to create and validate a brief instrument for measuring patient-based oral health outcomes associated with endodontic care in clinical settings and to test its psychometric properties.

3.2 OBJECTIVES

The objectives in support of the above aim are as follows:

- To review the existing core quality of life measures developed for the adult population and to generate an initial pool of items for an outcome measure questionnaire.
- For development of a brief measure/instrument and test it on adult patients presenting specifically for endodontic treatment at a local dental hospital primary care service.
- To Evaluate psychometric properties of the newly developed short-form instrument by testing it in a clinical primary care service for endodontic treatment of its reliability, validity and responsiveness.

3.3 NULL HYPOTHESIS

“The quality of life shows no improvement after completion of endodontic treatment”
The test of the hypothesis consists of providing treatment to patients presenting specifically for endodontic treatment at a local hospital, collecting and analysing quality of life data before and after care, and if data show a statistically significant change in the quality of life of patients the null hypothesis will be rejected.

CHAPTER 4 METHODOLOGY MATERIALS AND METHODS

4.1 INTRODUCTION

Guyatt's detailed approach for developing health related quality of life tools outlined in the paper by Juniper et al. (1997) was used for this study. The Guyatt's approach is the one the most widely used in the development of quality of life measures and has been used to develop a number of disease- specific outcome measures (Guyatt et al., 1989; Juniper and Guyatt, 1991; Baker et al, 1993, Guyatt et al., 1999; Cunningham et al., 2000).

The approach developed by Guyatt et al. (1985) can be divided into two phases (development and testing) and nine individual steps as follows:

Development

1. Specifying measurement goals.
2. Item generation.
3. Item reduction.
4. Questionnaire formatting.

Testing

5. Pretesting.
6. Reliability.
7. Responsiveness.
8. Validity.
9. Interpretability.

4.2 INSTRUMENT DEVELOPMENT

4.2.1 SPECIFYING MEASUREMENT GOALS

The investigator needs to decide on the primary purpose of the instrument. The primary purpose of the instrument was to develop and test a brief patient-based instrument for

evaluating the outcome of dental care in patients presenting for endodontic treatment in a primary dental care setting provided by undergraduate students. This stage helps to design appropriate development and testing of the protocols and enables other investigators to recognize the applicability of the instrument for use on their patients and studies conducted. The investigator should consider at least the following criteria:

4.2.2 PATIENT POPULATION

As it has been argued that the investigator may be thinking of a particular study in which the instrument is to be used, but constructing an instrument for too specific a population or function may limit its future usage. It is more feasible to choose a group of patient population that is narrow enough to allow focus on important impairments in that disease or function but broad enough to be used in other studies in future.

4.2.3 PRIMARY PURPOSE

The investigator needs to decide on the primary purpose of the instrument. Will the tool be used to differentiate between patients with different levels of health at one time (discriminative), detect important change over time in health status (evaluative), or predict future health status (predictive)? Juniper et al. (1997) have discussed that some instruments may be capable of all three functions but it is difficult that they will show maximum efficiency in all three. The primary purpose of the study was to develop a brief evaluative instrument for use in endodontic treatment within primary dental care settings.

4.2.4 PATIENT FUNCTION

In disease-specific instruments, investigators want to include all areas of dysfunction associated with that disease (physical, emotional, social and occupational), but the investigator has to decide whether all, or only specific functions are to be included. The patients in this study were specifically presenting for endodontic treatment in primary dental care setting, and thus the treatments include (both single and multi-rooted teeth).

4.2.5 OTHER CONSIDERATIONS

The investigator needs to decide on the format of the instrument. Will it be interviewing and/or self administered, is it suitable for telephone interviews. And a decision on how many items an instrument will contain? In this case it was decided that it will be a self administered questionnaire which will be handed over to patients before, during and after the endodontic treatment.

4.2.6 STAGE I (ITEM GENERATION)

This is the most important step in the development of a health status measurement tool. This step needs to be comprehensive as the final questionnaire can only include items identified at this point. As Streiner and Norman (1995) have stated" no amount of statistical manipulation after the fact can compensate for poorly chosen questions, those that are badly worded, ambiguous, irrelevant or-even worse-not present."

Methods used to generate relevant items include the following as recommended by (Juniper et al., 1996):

(I) a review of the disease-specific literature to identify items that may be appropriate for the description of the condition, global health instruments, existing disease-specific instruments and disease-specific questionnaires in related fields (Juniper et al., 1996).

(II) Health care provider's i.e. senior clinicians associated with the areas of care chosen who hold expertise in the care of patients with condition of interest need to be interviewed to provide their views on important items to be included as they may observe of the outward manifestations of a trait or disorder (Kirkley et al., 2003).

(III) Patients with condition of interest are interviewed. In this step most investigators will "sample to redundancy" (Streiner and Norman, 1995) by deciding, a priori, to stop interviewing new patients when no new items are generated. Patients to be interviewed should not be chosen randomly but Patient's to be interviewed be selected to represent the

full spectrum of patient demographics, disease categories and treatment experience and have some insight into their condition. Ideally purposive sampling technique should be employed as Patton (1990) has described the 'logic' and power of purposeful sampling lies in selecting information-rich cases for study in-depth. The information rich cases are those from which one can learn a great deal about issues of central importance to the purpose of research (Patton 1990). The patients being interviewed are asked to identify how their condition interferes with their quality of life using an open ended question format. They are then being asked more specifically about each of the domain that makes up the health.

Ideally the option (III) should be used involving lengthy detailed interviews between patients and independent interviewers which is an impractical approach in day to day clinical care. A simple self-administered questionnaire that is easy to understand and complete, which covers all the important aspects of HRQoL is a more realistic means of assessing health outcomes. The questionnaire needs to include all the relevant domains. The domains may cover physical, functional, psycho-social etc., and in case of disease, disease-related elements (Hester et al., 2001). Each domain consists of a number of dimensions (questions). However, Hester et al. (2001) have suggested that a balance must be found between the desire to include a sufficient number of dimensions so that a complete assessment of HRQoL can be made and the need to create a questionnaire that is not so long that it is burdensome for the patients to complete. They have further suggested that the advantage of combining questions into domains is that interventions can be directed at these domains in an attempt to restructure those negative aspects of health outcomes. The disease specific measures are more sensitive to disease-related changes in a patient's health status.

However, due to time constraints, consultation with researchers involved in the development of a number of quality of life instruments and a range of sound theoretical model based measures already developed and available, the decision was taken to conduct an extensive review of the literature (option I) examining the strengths and weakness of existing core and expanded oral health outcome measures/instruments to inform the development of an endodontic outcome measure (EOM). A comprehensive search for existing oral health outcome measures and generic outcome measures used in oral health that met the criteria set out in the protocol was conducted, using Medline, Web of Science, Pub MED, Social sciences citation indexes using key words identified from key papers in

the literature. Free searching was also done by searching relevant Medical and Dental e-journals as well as hand searching for done for those articles not available electronically. In the next step a review of the existing core and expanded oral health specific measures was conducted excluding all the measures specifically developed for children. This review was undertaken by taking in consideration the technicality of the measures i.e. the psychometric properties of the instruments such as reliability, validity and responsiveness and the theoretical model on which measures are based. In the last step key informants and tool developers were consulted. The focus of the consultation was the applicability, practicality of the potential tools and sample size required to develop this disease specific measure.

Based on the results of this review the research team (clinicians and Oral health research experts) along with consultation from statistician drafted a set of initial items in the new instrument.

4.2.7 STAGE II (ITEM REDUCTION)

This phase of the development involved deciding which items obtained from existing oral health outcome measures in stage I of the study should be discarded and which should be retained as appropriate for the final instrument. The goal of this stage of the study was to retain those items (which represent a reasonable respondent burden) that demonstrated the greatest impact on the patient population of interest and were also representative of the total concepts of health related quality of life. It is appropriate that patients themselves identify the items that are most important to them. The group of patients identified should represent the full spectrum of patient characteristics and disease variables of interest to identify those items that they have experienced as a result of their condition and for each positively identified item rates its importance to their overall health. For each positively identified item, patients can rate the importance using five-point, Lickert type scale (ranging from extremely important to non important). Based on this information, one can determine the frequency (the proportion of patients experiencing a particular item), the importance (the mean importance score for each item) and from this impact (the product of frequency and importance) of each item. Those items with the highest impact score should be selected for the instrument. However, there is no universally accepted method for item

reduction. Modern test theory methods may include structural equation modelling, confirmatory factor analysis, and methods based on item response theory (IRT), such as the Rasch analysis (Scientific Advisory Committee, 2002). Streiner (2007) has pointed towards a classical way the scree plot, where the eigenvalue greater-than-one rule is used to determine a number of factors. However, in 2002 in a review (Scientific Advisory Committee, 2002) have outlined the Classical test theory methods for examining dimensionality and evaluating an empirical measurement model include principal component analysis and factor analysis. Juniper et al. (1997) have outlined two approaches to item reduction: clinical impact testing or factor analysis. In this study to identify items for the outcome measure for endodontic treatment multicollinearity, factor analysis, linear regression and an expert based approach were used. This type of approach has already been used by Wong et al. (2007) to develop OHIP-aesthetics in which he has used both expert-based approach and factor analysis and linear regression to develop two types of OHIP-aesthetics measures.

The tool needs to be comprehensive which can be achieved by ensuring that all domains of health are represented. A comprehensive set of items will inevitably include some redundancies, but excessive redundancy should be avoided, especially in discriminative tools. This can be achieved by testing whether the items are highly correlated. If Spearman rank order correlations are high one can consider omitting one of the items.

4.2.8 ETHICS AND R&D APPROVAL

Approval for the wholes study was sought and obtained from King's College Hospital Research Ethics Committee (REC No: 05/Q0703/6) and from the Directorate of Research and Development at King's College Hospital NHS Trust R&D (R&D No: 05DS05) where the fieldwork was taken.

4.2.9 SAMPLE SIZE

Juniper et al. (1997) suggests that the investigator can select the sample size for the item reduction process by deciding how precise that wants their estimates of the impact of an

item on the population. The widest confidence interval around a proportion (the frequency with which patients identify terms) occurs when the proportion is 50%; any other will yield narrow confidence intervals. Juniper et al. (1997) has recommended that at least 100 subjects should be recruited for this part of questionnaire development as the confidence interval will be from 0.4 to 0.6. In research a wide range of recommendations regarding sample size in factor analysis has been made. Gorsuch (1983) has recommended five subjects per item, with a minimum of 100 subjects, regardless of the number of items. However, this has been challenged by Guilford (1954) who argued that N should be at least 200, while Cattell (1978) recommended three to six subjects per item, with a minimum of 250. Comrey and Lee (1992) provided the following guidance in determining the adequacy of sample size: 100= poor, 200 = fair, 300 = good, 500 = very good, 1,000 or more. (Cureton and D'Agostino, 1983) have recommended ideally several hundred excellent, just a large sample, as the sample size increases, sampling error is reduced, factor analysis solutions become more stable and more reliably produce the factorial structure of the population (MacCallum et al., 1999). However, MacCallum et al. (1999) have discussed that factor analysis can produce correct solutions, even with samples that would traditionally have been determined to be too small for meaningful factor analysis if data are 'strong', the impact of sample size is greatly reduced. Wong et al. (2007) have developed a short form of Oral Health Impact Profile (OHIP) for dental aesthetics (OHIP-aesthetic) by using 87 subjects; Allan et al (2002) have used 121 subjects to develop shortened version of the Oral Health Impact Profile (OHIP-EDENT) for assessing HRQoL in edentulous adults. Statistical advice was sought regarding sample size. We designed this study to have 80% power of detecting these differences, at the 5% significance level, for which samples of 110 patients were required. The total sample size of 110 patients allows multiple regression models to detect effect sizes of 0.38 while adjusting for potential prognostic factors like: age, social class, etc. and will yield 80% power to detect odds ratios of size 3.25 and larger for the proposed case-control study. However, considering a drop out ratio in the study 130 subjects were recruited in item reduction stage (Stage II).

A consecutive sampling technique which is a strict version of convenience sampling was used in both Stage II (item reduction) and stage III (Testing). In this sample the entire patient's with the condition within the hospital or clinic are included, not just those that the investigators happen to know about. This is a strict version of convenience sampling where every available subject is selected i.e. the complete accessible population is studied

(Kalton G 1983). This is the best choice of non-probability sampling since by studying everybody available, a good representation of the overall population is possible in a reasonable period of time. Explicit efforts were made by the researcher to identify and recruit all patients with conditions of interest by liaising with all key departments on a daily basis. The disadvantages of this sample are that it is non-random and can be biased. In these studies, the target population (i.e., patients presenting for endodontic treatment) were recruited for participation in item generation and psychometric testing of the instrument.

4.2.10 RECRUITMENT

Adult Participants (aged 18 years and over) were recruited from primary dental care settings associated with Kings College London Dental Institute (KCLDI). Posters were placed in reception areas to publicise the study. Patients were only booked for endodontic treatment when their acute phase had passed their other care had been undertaken. Patients at these clinics who met the inclusion criteria were provided with the study information sheet (Appendix B).The researcher liaised with senior clinicians at KCLDI to identify patients' willing to contribute to the research. Patients willing to take part in the study completed all the three stages of the questionnaires in Stage II of the study (pre- and post-endodontic treatment and at their one month follow-up visit). In Stage III of the study patients completed two sets of questionnaires (pre- and post-endodontic treatment).

Consent was obtained by asking willing participants to read and sign the consent form. Patients were informed that the questionnaire will not take more than 15 minutes to complete in stage II and not more than 05 minutes in stage III. A time convenient to the subjects was arranged by the researcher with the help of the supporting staff at the clinics as researcher was given access to their records just to keep record of patient’s appointments. Patients were reassured that refusal to take part will not affect the dental care they were receiving. The information sheet and the consent form can be found in Appendices (B) and (C) respectively.

4.2.11 INCLUSION AND EXCLUSION CRITERIA FOR THE WHOLE STUDY

The inclusion criteria for the study were:

- Age (18 years or over)
- Presenting specifically for endodontic treatment in primary dental care setting provided by undergraduate students.

The exclusion criteria were:

- Under 18 years of age
- Unable to provide informed consent
- Unable to read and write in English
- In acute pain.

4.2.12 STUDY PROCEDURES FOR STAGE II (THE ITEM REDUCTION STAGE)

Subjects were asked to participate in the study when presenting specifically for endodontic (RCT) therapy at KCLDI site. To control bias, subjects recruited to the study were assured that researcher would not be involved in their treatment and that their participation in the study will not influence the outcome of their treatment.

4.2.13 QUESTIONNAIRE FORMATTING FOR ITEM GENERATION AND ITEM REDUCTION STAGE

This phase of the instrument development is important as the questionnaire general format, instructions to the patients and the individual items need to be interpretable to patients. Streiner and Norman (1995) have recommended that each item needs to be checked for its reading level, ambiguity, double-barrelled questions, jargon, value-laden words, positive and negative wording, and length.

As the instrument is designed for use in the adult population, each item must be clear to a subject with reading skills at or below that of 12 years old child as have been suggested by Streiner and Norman (1995).

Ambiguity from the questionnaire can be minimised by clearly defining all terms and time frames in each item. The appropriate time frame may be variable depending on the treatment being evaluated or the population being studied. Juniper et al. (1997) have discussed that two weeks is commonly perceived as the upper limit of what patients can accurately recall. It is important to specify the time period for the question. In our questionnaire, because of feasibility constraints, we kept the reference period within last six months, as the recall time varied from subject to the subject because of appointment issues and waiting times at the primary dental care department. The literature review suggests that relatively short periods should be preferred over longer ones to generate to generate the most accurate data but currently there is very little research available to inform this question (Holden et al., 1985).

The items should be made as short as possible as Holden et al. (1985) found that the validity coefficient decreases linearly with the increased length of items.

In order to minimize the random error commonly known as noise the investigator has to choose a response format scale that had a number of options. It is beneficial to adopt a scale with more than two response categories (e.g. 'yes/no'). An evaluative instrument must be responsive to important changes even if they are small. The investigator usually chooses scales with a number of options such as Likert (1952) scale. With this format the subject indicates their agreement or disagreement with a statement on a scale consisting of adjectival categories that range from, for example (strongly agree to strongly disagree or not at all to extremely). The problem with this scale is that patients tend to avoid the two extremes of the scale (Streiner and Norman, 1995) and it has been recommended to use a nine level scale (Streiner and Norman, 1995) but it is difficult to find descriptors for nine levels of a single item. Between five and seven categories are therefore recommended as the optimal number of response options (Streiner and Norman, 1995). The other method is simply visual analogue scale. This is a line of fixed length (100 mm) with anchors at the extreme ends. Respondents involve mark a line or a cross on the scale at the point that corresponds to their estimation of the amount of impact that they experience. A number of studies have found little difference in the efficiency of visual analogue and categorical scales (Remington et al., 1979; Slevin et al., 1988). However, the lack of familiarity with the VAS has resulted in more inaccuracies in completing these scales. One study found that 7% of the respondents had completed VAS inaccurately (Huskisson, 1974). The

Lickert five to seven scales has practical advantages over the VAS, being easier to administer and easier to interpret (Jaeschke et al., 1990).

At the end of reduction phase the investigator has the required number of items in the questionnaire. These items can be grouped into domains or dimensions by the researcher by reviewing the items and using common sense, clinical experience, and domains described in established instruments to group the items.

4.2.14 ORAL HEALTH-RELATED QUALITY OF LIFE INSTRUMENT FOR STAGE II (THE ITEM REDUCTION STAGE)

During the first visit subjects were asked to complete a five section questionnaire consisting of (Appendix F):

- Self/Global oral health rating question.
- A visual analogue scale (VAS) for pain.
- Items derived from review of existing oral health outcome measures (Chapter Five).
- Socio-demographic information.

In this stage of the study patients were invited to complete three questionnaires. The first has been just prior to embarking on endodontic therapy. Postoperatively there were asked to complete a second questionnaire after completion of endodontic therapy (Appendix G). They were invited to complete a third questionnaire at one month follow-up visit (Appendix G). A new section was added to the same questionnaire and was used at the end of episode of care and at the follow up appointment. A global transition judgment question was added in the new section to assess self-perceived change in oral health by the subjects at follow-up (Appendix G).

4.2.15 STATISTICAL ANALYSIS FOR STAGE II (THE ITEM REDUCTION STAGE)

Data were entered into SPSS Version 15.0. Multicollinearity, factor analysis and linear regression analysis were performed by using SPSS version 15.0 (SPSS Inc, USA).

4.2.16 EXPERT BASED APPROACH FOR STAGE II (THE ITEM REDUCTION STAGE)

Based on the statistical results the researcher along with consultation from statistician drafted a set of initial items in the new instrument. All clinicians in the primary dental care setting supervising endodontic treatment provided by undergraduates were also contacted to give comments and suggestions for improvements. This approach provides the assessment related to comprehensibility (wording and clarity of specific items) and relevance to the treatment and whether the item must be retained, revised, rejected or added.

Experts in the field must also indicate whether or not the item corresponds to the domain (subscale) assigned. Experts could also make general suggestions for changes or new items not included. The criteria established to decide on retention, modification, rejection or addition of items was consensus of more than 80% among the experts. A new item worried was added to the questionnaire by using this approach in the final questionnaire.

This approach has also been outlined by Guyatt et al. (1985) for each stage of instrument development and has been applied in a number of studies (Guyatt et al., 1992; 1993).

4.3 STAGE III (INSTRUMENT TESTING)

4.3.1 SAMPLE SIZE

The sample size for validation of the study was small and homogenous but was very similar to the studies conducted by Guyatt et al (1992; 1993) for validation of the Asthma Quality of Life Questionnaire in which they reported consistent results despite the small sample size. The study purpose can affect the sample size Bryce et al (2007) have discussed that a larger samples are difficult to obtain in health outcome research but have further discussed that this limitation may be addressed by a heterogeneous sample to reflect the characterises of the subjects involved in the study. Although the testing stage of the study was performed with a small sample size, the results on psychometric data were encouraging. The level of

significance was statistical significant as p-value was less than the significance level of 0.05. Statistical advice was sought regarding sample size for this stage of the study.

4.3.2 PRETESTING

This stage involves identification of any problems with the final set of items on the questionnaire, the response options and the instructions to the subjects. It is wise to pre-test the instrument on a small number of patients to identify and resolve these problems before embarking on a costly and complex validation study. The clarity of wording and the interpretation of each item need to be evaluated. A group of subjects ranging from five to 10 are asked to read the items and to give an interpretation of each item to an interviewer. Any items that subjects partially or fully misinterpret are revised. The revised questionnaire is administered to another group of patients and this process is repeated until no more changes are needed. The questionnaire was administered to five endodontic patients at the dental hospital and selection criteria were to represent as wide spectrum as possible. Only layout changes were made in the final questionnaire to make it clear for the respondents. No further changes were needed.

4.3.3 TESTING STAGE OF THE INSTRUMENT

The newly developed instrument (Appendix I and J) was administered to a further sample of 30 (n=30) adult patients (ranging in age from 18 to 64 years) presenting themselves at KCLDI for endodontic (RCT) therapy. Patients were asked to complete the short endodontic outcome measure before and after the completion of treatment to enable data analysis to test for validity, reliability, responsiveness, and interpretability the basic criteria for acceptable psychometric properties of any evaluative instrument (Juniper et al., 1997).

4.3.4 STATISTICAL ANALYSIS FOR STAGE III (THE ITEM GENERATION STAGE)

Data were entered into SPSS version 15.0. The analysis involved descriptive statistics (prevalence, severity item mean of each item, 95% confidence interval) and psychometric analysis involved paired t test, Wilcoxon test, Cronbach's alpha values and Multivariate linear regression analysis. Data analysis was performed by using SPSS version 15.0 (SPSS Inc, USA).

4.3.5 RELIABILITY

Reliability is concerned with the reproducibility and internal consistency of a measuring instrument. The term reliability has many synonyms including reproducibility, repeatability and precision. All of these terms however, have the same concept that repeated administration of a measurement tool to stable subjects will produce the same results. It assesses the extent to which the instrument is free from random error and may be considered as the amount of a score that is signal rather than noise (Fitzpatrick et al., 1998). The reliability of a particular measure is not a fixed property but it is dependent upon the context and population studied (Streiner and Norman, 1995).

As most of the health related quality of life measures are self-administered, inter-rater reliability is therefore not relevant for self-report questionnaires as they do not involve raters or observers.

Test-retest reliability is the degree to which an instrument reproduces stable scores over time in respondents who are assumed not to have changed on the domain being assessed. It is the relationship between scores obtained by the same person on two or more separate occasions (Hays et al., 1993). The tool measures in stable subjects twice separated by a short interval. The test-retest reliability is usually expressed by Pearson or intraclass correlation coefficients (ICC), with a recommended minimum criterion of .70 (Scientific advisory Committee, 1995). The ICC is the proportion of total variability accounted for by the variability among individuals. This statistic assesses not only the association between repeated measures but also the agreement (Guyatt, 1987). As ICCs are sensitive to

systematic changes and also to the strength of the correlation and as such are increasingly recommended for reporting test-retest reliability (Deyo et al., 1991).

Reliability is not a property that a tool does or does not possess it is a range and is specific to the population and the circumstances under which it is evaluated. Since the ICC is a ratio between subject variance, the value will be artificially elevated by testing on a very diverse population and will be artificially lowered by testing on a homogeneous population. Therefore the patients chosen to take part in the reliability testing of the instrument must be selected to represent the population in which the instrument is to be used. However, Guyatt et al. (1985) have discussed so with a questionnaire about quality of life we are interested in detecting change within subjects over time thus the magnitude of the variability between subjects is irrelevant and correlation coefficients may give misleading results.

Parallel forms reliability is rarely used in the HRQoL assessment as few measures have parallel forms due to the practical constraint of having to develop two measures of the same outcome (Hays et al., 1993; Kaplan et al., 1997).

Researchers often report on another measure of reliability called internal consistency as measured by Cohen's kappa. It measures the extent to which items in a scale measure the same concept. Internal consistency (equivalence) is the extent to which all items in the scale measure aspects of a single attribute rather than different attributes. This is often measured using a test called Croanbach's alpha and the score should be between 0.70 and 0.90 (Croanbach, 1951, Nunnally and Bernstein, 1994, Streiner and Norman, 1995). If the score is cited as less than 0.70 this is generally concluded as meaning the measure does not show internal consistency. It is important to note that internal consistency reflects both the number of items in a scale and the average correlation between items (Nunnaly, 1994). As this a measure of how well the items in a tool "hang" together but it is possible that two items discriminate well between patients of differing severity but are not highly correlated. It has been argued that excessive attention to internal consistency can result in the omission of important items, particularly those that reflect the complexity and diversity of a phenomenon (Donovanon et al., 1993). The researchers have decided it makes more sense to error on the side of patient opinion; therefore they do not give much value to

measure internal consistency by dropping those items which have high impact (Fitzpatrick, 1998).

Cronbach's alpha values were calculated of the newly developed measure.

4.3.6 RESPONSIVENESS

This is the ability of the measure to detect true change in patients' status over time (Juniper et al., 1997) that is, is it sensitive to the subtle yet important changes patients make. An evaluative instrument requires good responsiveness. The instrument must be able to detect small changes. The signal from an evaluative instrument is the true change occurring in a patient over a period of time. This change may occur spontaneously or as the result of an intervention. A responsive scale has advantages that the sample size required to detect a given difference will be less than that required using a less responsive tool reducing cost and time factor and the second advantage is to identify the patient characteristics that are predictors of success by identifying those patients who respond to treatment compared with those who don't.

Several tests have been proposed to quantify responsiveness like Responsiveness Index (Guyatt et al., 1985), the Standardized response Mean (Cohen, 1977) and the Effect Size (Kazis, 1989) but no one test has become a standard. There a number of approaches to testing responsiveness (Juniper et al., 1997). A three strategic approach has been used that address the following questions:

(a) Can we measure this change in patients who truly change their health status (using a paired t-test to compare baseline and follow-up score)?

(b) Is the instrument able to distinguish between those patients who change and those who stay stable (using an unpaired t- test to determine if the magnitude of change in instrument score differs between stable subjects and those who's HRQOL has changed)?

(c) What is the magnitude of the instrument's responsiveness index?

This index is calculated from the minimal important difference (MID). The MID has been defined as "the smallest difference in score…which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive costs, a

change in the patient's management" (Jaeshke et al., 1989). From the responsiveness index it is very simple to calculate the sample size need for both parallel group and crossover clinical study designs for various levels of type 1 (alpha) and type 2 (beta) error rates (Juniper et al., 1993). The ETA squared test, observed mean change of overall scores before and after treatment and the effect size was calculated to confirm responsiveness of the measure.

4.3.7 VALIDITY

An instrument is valid if it is actually measuring what it is supposed to measure (Guyatt et al., 1989). Validation is clear cut when there is a gold standard to which results can be compared; however, a gold standard for quality of life does not exist. As the face validity refers to the overall appearance of the instrument to the people who are going to use it. It is important for clinicians' acceptance of an instrument. However, it has been clearly demonstrated that physicians are poor judges of patient outcome (Hayworth et al., 1981) and are poor judges of what is important to patients, and as the patients' opinions are used to generate items for the questionnaire so the formal evaluation of face validity is not necessary.

Construct validation is the major category for validation of health related quality of life instruments. An instrument has construct validity when it correlates with other measures as could be predicted if it is really measuring what it is supposed to measure. Construct validity requires several predictions about how the results of the questionnaire should correlate with other related measures and then testing of these hypotheses.

For discriminative instruments one establishes construct validity by examining the relation between scores on the new instruments and other indices at a single point in time.

Evaluative instruments are primarily concerned with measuring change; one must examine the correlations between change in the overall HRQOL and in each of the domains of the new instrument and changes in other indices of impairment (Guyatt et al., 1985). The actual correlations are then compared to the priori predictions as an indicator of validity.

Osoba 1998 has suggested contrasting the convergent validity of HRQoL instruments global measures of oral health can be included in the study as they are simple to use. Atchison and Dolan (1990) used a single item global rating of oral health (rating dental health as excellent, very good, good, fair or poor). A moderate correlation was observed between GOHAI and global rating data. However, it has been reported that this measure is a potentially valuable outcome measure despite perceiving oral health rather than the impact of oral disease (Bowling, 1995; Atchison and Gift, 1997; Dolan et al., 1998). This measure has been used as a simple and economically feasible measure to summarise the state of an individual's oral health (Gift et al., 1997). Matthias et al. (1995) suggested that as it focuses on health instead of disease so it has a more positive approach; however, it has limitations as it is simpler and less precise. The global transition judgement scale was also included in the measure in post-treatment questionnaire of the measure. These measures also have the advantage of simplicity, clarity, ease of use and analysis (Locker 1998). These measures capture the perception of change in oral health of the patient after completion of treatment by a single item (rating dental health as worsened a lot; worsened a little; stayed the same; improved a little; improved a lot). MacKenzie et al. (1986) have suggested that such measure is used as a gold standard when evaluating the sensitivity to change of health related quality of life measures. However, Locker et al. (2004) have raised concerns about the psychometric properties of these measures and have suggested further testing in particular the relationship between these single item measures and oral health related quality of life requires clarification.

Validation is far stronger if investigators have made a priori predictions about how the instrument should relate to existing measures, if it is actually measuring what it is intended (Juniper et al., 1997).

The validity estimate is not a property of the instrument, but is a property of the instrument when administered to a specific sample under specific circumstances.

Convergent validity of the newly developed measure was measured by including the self rating of oral health questionnaire in the pre-treatment questionnaire and both it and the global transition judgment scores were also included in the post-treatment questionnaire of the newly developed measure.

4.3.8 INTERPRETABILITY

Interpretability means what do the results mean? Clinicians can make meaningful interpretation of results because of repeated experience with physical examination and laboratory determination of disease and dysfunction in the patients that they evaluate frequently. Patient based outcome measures lack interpretability this may be due to lack of familiarity with use as health professionals seldom use HRQoL measures in clinical practice. Interpretability is defined as the degree to which qualitative meaning can be assigned to quantitative scores derived from an instrument (Scientific advisory Committee, 1995). Clinicians need to able to make meaningful interpretations of results. Some leading health outcomes methodologists purpose the use of clinical data to help calibrate HRQoL measures and facilitate interpretation (Kaplan et al., 2000; Testa, 2000).

Researchers have begun to make efforts to make scores more interpretable (Testa and Simonson, 1996). Testa et al. (1993) in a trial of antihypertensive drug used a method to calculate change scores on QOL instruments with the change for the same instruments that have been found with major life events such as job loss. In this way health related scores could be related to other human experiences that have clear and perceptive meaning.

Another approach is interpreting the results is to identify a reasonable range within which a minimal clinical importance difference (MICD) falls (Jaeschke et al., 1989; Juniper et al., 1994). The MICD has been defined as " the smallest difference in the score which patient perceives as beneficial and which would mandate, in the absence of troublesome side effects and excessive costs, a change in the patients management" (Jaeschke et al., 1989). The determination of the MICD is not only important for judging the magnitude of the benefit when comparing treatments, but also for calculation of sample size for clinical trials and to estimate the proportion of patients that will benefit from an intervention (Wright and Young, 1997). Juniper et al. (1997) have estimated the minimal important clinical difference by examining the relation between the global rating of change questionnaires that are administered to the patients at each follow up visit during a validation study, and the HRQoL instruments scores. Patients were asked whether they have experienced any change in the outcome of interest since the last clinic visit. When using seven point response options, a mean change of 0.5 per item represented a minimal

clinically important difference, a change of 1.0 per item represented a moderate change in HRQoL, and a change in 1.5 per item represented a large change. As pointed out by Juniper et al. (1997) this change represents a within person change and does not necessarily indicate that a difference of this amount will signify a minimal important difference with the instrument when used to discriminate between patients.

Another means for interpreting the results is through comparison with 'norms'. The sores of a normal population, i.e. general population, or disease specific population, with measures are tabulated and published. This information only tends to be available for generic measures e.g. SF-36 (Fitzpatrick et al., 1998).

The difference in change of score before and after treatment of the newly developed measure was calculated for the minimal important clinical difference.

4.3.9 PROTECTING CONFIDENTIALITY IN STAGE II AND III

Participants were given written and verbal assurances that their responses to questionnaires would treated confidentially. Questionnaires were pseudo-anonoymised, bearing the participant's allocation number rather than their name, and kept in a locked cabinet in a locked room at KCLDI.

Signed consent forms and any other participant-identifiable written material was stored separately in a locked cupboard in the Department of Oral Health Services Research, KCLDI. Only the researcher (TR) and Principal Investigator had access to the list that matches an allocation number with participants. All data held on computer were anonymised and password-protected.

4.3.10 DATA STORAGE IN STAGE II AND III

In line with KCL requirements, data are stored for seven years after the end of the study. Data will be removed from computers after data analysis is complete and stored on a CD-ROM, together with copies of the research protocol, a copy of the COREC application, etc.

Together with original data forms, they will be sealed in boxes and stored securely for the required period.

4.4 SUMMARY

This chapter has outlined the methodology and methods for construction of a disease-specific measure that can be applied to specific-conditions. Endodontic treatment is such a condition. This approach outlined should make construction of disease specific measure less intimidating and improve the responsiveness and validity of the measure (Guyatt et al., 1985; 1996). This section outlines a three stage approach to outcome measure development involving item generation, item reduction and testing stages informed of work approach of Juniper et al (1995) and in line with the approach taken by Wong et al (2007). This chapter leads into three chapters of results as outlined below:

- Chapter Five (Item generation stage)
- Chapter Six (Item reduction stage)
- Chapter Seven (Testing stage)

CHAPTER 5 RESULTS STAGE I (THE ITEM GENERATION STAGE)

5.1 INTRODUCTION

This chapter reports a brief but concise overview of the existing core oral health outcome measures which were reviewed to generate an initial pool of items for the Endodontic outcome measure (EOM) as outlined in objective I in chapter III. Some of the core oral health outcome instruments are being discussed in this chapter to encompass their strength and weaknesses as well as their use as an outcome measure. The Over the last five decades researchers have generated a range of patient-based instruments designed to measure health, functional status and the importance of health in daily living, starting with a focus on quality of life and moving on the examining health related quality of life. In dentistry, there has been considerable methodological research leading to the development of questionnaire instruments over 30 years ago to measure dimensions of quality of life that relate to oral health stimulated by Cohen and Jago (1976) who advocated the development of "socio-dental" indicators, following the example of our medical counterparts. The American Dental Association (1985) followed by recognizing the importance of social and psychological factors in shaping the future of the dental profession and suggested that "the behavioural and psychosocial aspects of dental treatments will play an increasingly important role in patient management and will become an integral part of dental practice and dental treatment".

5.2 THE LIMITATIONS OF THE EXISTING CORE ORAL HEALTH QUALITY OF LIFE MEASURES BEING USED AS AN OUTCOME MEASURE

Various methods have been used to measure OHRQoL ranging from the use of existing generic health questionnaires (Reisine, 1988) to specifically designed dental instruments with up to 56 questions (Cornell et al., 1997). Reisine (1988) used the Sickness Impact Profile (SIP), a generic instrument developed by Bergner et al. (1981), to measure oral

health outcomes. The SIP was useful to evaluate functional status where the impacts of dental conditions were high. However, it was reported to have limited application in assessing general oral health status because of lack of sensitivity to oral health problems (Reisine, 1988). Gooch (1980) raised similar issues in relation to the RAND Dental Health Index where three oral health related questions were added by Ware et al. (1980). The ability of a limited number of items in a generic measure to comprehensively assess the psychological and social impact of dental disease has been called into question (Locker, 1988). Thus, began the development of oral health indicators.

Atchison and Dolan (1990) used the theoretic construct (physical, social and psychological) to develop an index of the impact of oral disorders to develop 'General Oral Health Assessment Index' (GOHAI). It was developed from a review of the literature and consultation with health care providers and patients, rather than just being based on a theoretical model. Cushing et al. (1986) developed 'Social Impacts of Dental Disease' (SIDP) based on health status model focusing on the three major aspects of an individual's health status; the physical, the social and the psychological. Strauss (1993) developed the Dental Impact Profile based on the evaluation of patient's perceptions by the salience of events. The Oral Health Impact profile developed by Slade and Spencer (1994), the Subjective Oral Health Status Indicators developed by Locker and Miller (1994), the Dental Impact on Daily Living developed by Leao and Sheham (1996), the Oral Impacts on Daily Living developed by Adulyanon and Sheiham (1996) all are based on the WHO classification of Impairments, Disabilities and Handicaps (WHO, 1980) and the Locker's theoretical framework for measuring health outcomes (1988). The most recent instrument, the Oral Health Quality of Life (UK) developed by McGrath and Bedi (2000) is based on an updated WHO model of 'structure-function-ability-participation' (WHO, 1998). All of these measures seek to capture the frequency and severity of oral problems in functional and psychosocial well being (Allen, 2003).

The majorities of the instruments are well designed, well tested for psychometric properties and appear to be theory based. This review is limited to three instruments that have been widely used, well tested for their responsiveness; the latter is defined as "their ability to detect minimal important clinical changes" (Locker, 2004).

5.3 GERIATRIC (GENERAL) ORAL HEALTH ASSESSMENT INDEX (GOHAI)

GOHAI has been widely used and has been proven to measure aspects of life that are regarded important by the subjects (Locker et al., 2001; Locker et al., 2002; Jeannin et al., 2003; Veyrune et al., 2005). Mascarenhas (1999) has recommended GOHAI for use as an outcome measure in the evaluation of dental treatments. In a study conducted on elderly people the researcher has reported that GOHAI was sensitive in differentiating between individuals actively seeking care and those not seeking care. The index has been found valid for use in younger adults (Atchison et al., 1998; Tubert et al., 2003) with satisfactory psychometric properties among ethnically diverse samples (Atchison et al., 1998) and has been referred to as the General Oral Health Assessment Index and has been referred to as the General Oral Health Assessment Index by Atchison (1997). Dolan (1997) evaluated the sensitivity of GOHAI to dental treatment with other self-reported measures of oral health, and findings suggest that the GOHAI is sensitive to the dental treatment provision.

Atchison et al. (2006) by using GOHAI in a surgical outcome study reported that it was sensitive to detect changes that are clinically important such as difficulty in biting or chewing and feeling discomfort during eating. Veyrune et al. (2005) reported that GOHAI is able to detect oral health changes over time and to measure the effects of oral treatments in patients receiving new prostheses. Patients who received new dentures have reported improvement in GOHAI scores as compared to other subjects and significant associations were also found between variation in GOHAI scores and responses to general questions on changes in state of oral health (Dolan, 1997; Dolan et al., 1998).

The German version of GOHAI had sufficient reliability, validity and responsiveness to be used as measure of oral health-related quality of life in cross-sectional and longitudinal studies of the elderly (Alexander et al., 2008).

Although Dolan (1997) has suggested that GOHAI has the potential to evaluate the appropriateness and effectiveness of dental therapies, Slade (1997) has raised concerns about its appropriateness for use with younger age groups because of its content validity given that it was primarily developed to estimate the degree of psychosocial impact associated with oral diseases in older populations.

In summary, GOHAI is important because it includes positive aspects of oral health and it is a short and readily administered and has been validated as an outcome measure against a global oral health rating (Dolan et al., 1998).

5.4 Oral Health Impact Profile (OHIP-49) & shortened forms of OHIP

OHIP is the most widely used OHQoL measure. OHIP is considered one of the most sophisticated and most popular instruments for measuring OHRQoL by key researchers in this field.

Awad et al. (2000) have reported that OHIP has shown a good potential for use as an outcome measure in a clinical trial in which different treatments for edentulism are compared, and reported that patients receiving implants retained dentures reported significant improvements in oral health status as compared to subjects receiving conventional dentures. Subjects in the implant group experienced improvements on all seven dimensions of OHIP, while subjects in the conventional group experienced improvements in only functional limitations and physical disability (Awad et al., 2000). Allen et al. (2003) used OHIP as an outcome measure to assess the impact of oral implant therapy on the psychosocial well-being of subjects with a complete denture wearing problems; subjects who had severe problems wearing complete dentures and were seeking treatment with dental implants reported a negative impact on quality of life parameters from the OHIP questionnaire.

Biazevic et al. (2004) in a study conducted to investigate the impact of oral health conditions on the quality of life of the elderly people have used OHIP; they have reported that most participants experienced several impacts affecting their daily life: speech, alteration in flavour of foods, pain, food intake discomfort, uneasiness, stress, reduction in food intake, interruption of meals and embarrassment. McGrath et al. (2005) have tested OHIP's sensitivity and responsiveness for tooth whitening procedure and have reported that observed changes were apparent in all overall OHIP scores and across several domains, notably functional limitations.

However, this instrument is not without its limitations, primarily related to its length. Slade (1997) reported a poor response rate where participants have difficulties in reading. Locker and Allen (2002) have reported that as the measure is too long it is quite likely that the subject's non response rate is likely to be high. Wolfart et al. (2005) reported participant burden when using OHIP. It focuses on negative aspects of oral health but it is one of the few measures of oral health that incorporates the social dimension of health thoroughly. It is based on ICIDH conceptual structure, but remains well aligned to the new concepts of the ICF (Slade, 2002).

All versions of the Oral Health Impact Profile have been tested extensively and shown to have good construct, discriminative and longitudinal validity when tested in different settings and conditions and also has been validated as an outcome measure against a global oral health rating (McGrath et al., 2005).

In summary OHIP-49 is the most robust and comprehensive measure of OHRQoL to measure oral health outcomes; however, because of its length, it proves more of a challenge to use, a shorter form of OHIP, the OHIP-14 was developed (Slade, 1997). The compromised instrument in terms of content validity was derived using internal reliability, factor and regression analysis (Slade, 1997).

5.4.1 OHIP-14

Allen and Locker (2002) and Locker and Allen (2002) have demonstrated that short–form OHIP's, comprised of different subsets of items, detect more change and suggested their use as an outcome measure in clinical trials or evaluation studies that require a shorter instrument. Modified versions of OHIP reflect improvements in oral health related quality of life of patients with implants. However, OHIP-14 was not able to detect any clinically meaningful changes because the majority of patients frequently reported problems in chewing food or were unable to chew food. These items are excluded from OHIP-14; it is likely a reason for the poor responsiveness of the OHIP-14. Lewellyn et al. (2003) have reported that high impacts regarding functional limitations, physical pain and psychological discomfort were recorded when OHIP-14 was used to assess the impact of stomatological disease on oral health related quality of life. McGrath et al. (2003) in a

study evaluating the performances of patient-centered outcome measures after oral surgery have reported that OHIP-14 scores were associated with clinical findings and that the measure was sensitive and sensate in relation to oral surgery. McGrath et al. (2003) have also reported that it is sensitive to the clinical effects of topical betamethasone in the treatment of oral lichen planus. Robinson et al. (2003) used OHIP-14 in a primary dental care hospital setting in the UK and reported that OHIP-14 correlated more closely to the presence of a dental problem, described pain and self reported oral health status; however, they also described the limitations of OHIP-14 concluding that it is more suitable for comparing groups and suggesting its usage for population level questionnaire based research.

Locker et al. (2004) have also reported that OHIP-14 appeared to be responsive to change when it was used to evaluate a dental care programme for older people; however, the magnitude of change it detected was modest probably because it was primarily designed as a discriminative measure. OHIP-14 showed mean change scores for its three subscales (functional limitation/pain, psychological impacts, and social impacts). These subscales were conceptually based rather than derived from statistical procedures and as, Locker et al (2004) have discussed, and it was not possible to use the seven domains compromising the long-from OHIP. However, the results showed that the association was statistically significant for the social impact subscale only.

Scott et al. (2004) have used OHIP-14 as an outcome measure to assess the impact of the original dentures and replacement dentures on patients oral health related quality of life and reported that the provision of new dentures did not result in major changes to the OHIP-14 scores. Subjects reported significant improvements in the OHIP-14 scores in relation to taste, discomfort during eating, self-consciousness and embarrassment.

Baker et al. (2006) have used OHIP-14 in a specific clinical context: patients with xerostomia and have reported it as a useful measure of OHRQoL in this population. Overall, OHIP-14 performed better than OIDP (Baker et al., 2006). After conducting a long standing prospective cohort study, Thomson et al. (2006) have reported a strong association between xerostomia and OHRQoL by using OHIP-14. Overall every OHIP dimension had at least one item which was associated with xerostomia. Fernandes et al. (2006) by using OHIP-14 in general dental practice have reported that it is a valid and

reliable measure of oral health-related quality of life and is responsive to third molar clinical change. A study conducted to evaluate the effect of rehabilitative dental treatment on the oral-health-related quality of life and employment of welfare recipients have reported that there was a significant change in OHIP-14 scores after treatment which led to improved oral health quality of life and employment outcome of this welfare population (Hyde et al., 2006).

OHIP-14 was used in the Adult Dental Health Survey (1998) as a population survey tool. It was used to assess a basic overall measure of the impact of oral health on a national basis. Physical pain and the psychological impact of oral conditions have been the most frequently reported problems. Kelly et al. (2000) reported that people can be affected in different ways by their oral condition and that for some the impact can be sufficiently serious that their lives are affected.

In summary, OHIP-14 is a useful measure for examining oral health impacts at the population level its responsiveness have been evaluated against a global oral health measure (Locker, 2004) but its compromised content validity makes it less helpful as an outcome measure than the OHIP-49.

5.4.2 OHIP-20

Heydecke et al. (2002) developed and used OHIP-20 as an outcome measure in assessing the impact of mandibular implant over dentures and conventional dentures in senior subjects; comparison of the pre- and post- treatment ratings showed that significant positive change had occurred in the implant group as compared to conventional denture receiving group. It is comprised of OHIP-14, plus an additional six questions from OHIP-49, including questions on chewing. Heydeke et al. (2002) reported that the implant over denture group had a significantly better oral health status than the conventional denture group six months after treatment. This was expressed in significantly lower scores in four OHIP-20 domains: functional limitations, physical pain, physical disability and psychological disability - no between group differences were observed on the remaining domains: psychological discomfort, social disability and handicap scales Heydeke et al. (2002).

5.5 Oral Impact on Daily Performances (OIDP)

This measure is based on the same theoretical model as OHIP and has the advantage of being short and focuses on the main consequences of oral impacts (physical, psychological and social). Locker et al. (2004) have reported that this instrument is responsive to change. It has been used as an outcome measure by Robinson et al. (2005) but it was reported that no significant difference in total score of OIDP was noted following the provision of a reservoir bite guard for patients with xerostomia. Baker et al. (2006) have used it as an outcome measure to measure OHRQoL of patients with xerostomia, it performed well and had good psychometric properties, but overall OHIP-14 performed better. Melas et al. (2001) have also reported that it is difficult to assess the responsiveness of the measure as a whole. However, it has a poor completion rate by people of other ethnic origin in comparison to OHIP-14 in a dental hospital setting at a primary care department in the UK (Robinson et al., 2001). In addition, it fails to the incorporate individual's perceptions of the study population (Slade, 1997).

In summary, there is insufficient published evidence to choose OIDP as an outcome measure over the other existing measures currently available and its responsiveness has not been evaluated against a global oral health measure.

5.6 Oral Health Related Quality of Life (UK) (OHQoL UK)

This measures both positive and negative dimensions of OHRQoL. It is based on an updated WHO model of 'structure-function-ability-participation' (WHO, 1998). The measure has shown good psychometric properties and has better content validity but it has been used only in a very few studies as an outcome measure. In a study Mc Grath et al. (2003) have reported that it was sensitive to deterioration in oral health status after removal of third molars surgically. However, at six month review, in comparison with OHIP-14 it was less sensitive in relation to preoperative status than OHIP-14. In a study looking at the clinical effects of a topical steroid in the treatment of Lichen Planus OHQoL (UK) performed as well as OHIP-14 in terms of sensitivity (Mc Grath et al., 2003).

In summary, by combining positive and negative dimensions of oral health, OHQoL UK has potential as a measure of outcome; however, further development is required as the open ended questions used in the study are difficult to interpret and most importantly the copyright issue has proved a barrier to its usage.

5.7 SUMMARY

Whilst all of the existing validated measures have their strengths in measurement of OHRQoL, they have recognized limitations as clinical health outcome measures as outlined below:

The majority of oral and dental instruments developed are generic and thus they detect the impact of oral and oro-facial disorders in general (Locker et al., 2001). These measures are useful in that they allow comparisons across diseases and conditions; however, they may suffer diminished sensitivity, specificity and utility when used with a particular disease (Locker et al., 1997).

Locker (1996) has reported that OHQoL measures have many potential applications but have been used almost exclusively in oral health surveys of populations of adults or older adults rather than in clinical trials or clinical or public health practice. It is recognized that further work is needed to develop standardized outcome measures that are easily applicable in dental practice (Bader et al., 1999), and to make OHRQoL more user-friendly (Williams et al., 2004). Allen (2003) suggested that the measures which use weighting to assess the severity of an impact are considered to be better outcome measures, whilst recognizing that the weights increase the complexity of use and interpretation of these measures in a clinical setting. McGrath and Bedi (2004) also suggest that further work is required to determine the value of weighting when specific clinically evaluated conditions are assessed. Locker (2004) has recommended that data obtained from these types of measures can be used to assess the relative cost-effectiveness of different types of treatments and can be helpful in assisting in finding ways of obtaining the most health gain from shrinking health care resources. These types of measures are essential in allowing clinicians and researchers to address important questions concerning the delivery of dental health care (Locker, 2004).

In conclusion, the findings of this review suggest that at present no single instrument can be regarded as a standard, being comprehensive and robust enough to capture all aspects of OHRQoL and act as an outcome measure for clinical care. The existing measures explore the impact of oral health and disease on daily functioning. These are predominantly generic as they are intended to assess OHRQoL across a range of different oral health conditions, but tend to lose validity and reliability when used for a particular dental disease. There is a need for an OHRQoL measure that can be used in a clinical setting, as existing measures have been predominantly employed in general or primary care population surveys. There is room for a simple brief patient-based outcome measure that is valid, reliable and sensitive to the interventions provided for dental diseases that should be able to measure within-subject changes in a clinical setting. Research is needed to draw on elements of existing instruments, both negative and positive, test and retest them in clinical settings, and then to develop disease specific items based on the results from those instruments for measurement of within-subject changes in clinical settings which should be comprehensive, short, easy to administer so that the newly developed tool can be used in clinical practices routinely.

It was decided to use 58 items both from OHIP-49 and GOHAI to develop a new outcome measure used in stage II of the study the item reduction stage (Appendix:F) because:

- Reliability and validity of the both instruments have been proven (Atchison KA 1997; Locker and Slade.,1993);
- Cross-cultural consistency of both has been reported Allison et al (1999) and this is particularly important in a setting such as London with its ethnic diversity;
- The majority of the key researchers involved in developing outcome measures agree that the OHIP-49 could be described as an expert-centred measure of subjective oral health that may be capturing events which impact on general well-being and quality of life. As well a systematic review concluded the psychometric properties of OHIP-49 and reported that the instrument is sensitive enough to capture changes in the impact of oral conditions (Miotto et al., 2001);
- OHIP-49 captures the full spectrum of impairments and discomforts unlike the OIDP which measure more significant oral impacts (Tsakos et al., 2001);

- GOHAI is sensitive to the dental treatment provision; contains both negative and positive items (Atchison and Dolan., 1990) like OHRQoL (UK) but copyright issue is a major barrier in using OHRQoL (UK);
- GOHAI is generally more accurate in terms of detecting impacts in the form of pain and dysfunction (Locker et al., 2001);
- OHIP is better at detecting psychosocial impacts (Locker et al., 2001).

The next chapter describes the item reduction stage and the development of the short form of measure for endodontic treatment by using both statistical and expert based approach after this long instrument developed from stage one was tested and applied to patient's specifically presenting for endodontic treatment provided by undergraduate students at a primary dental care setting.

CHAPTER 6 STAGE II (ITEM REDUCTION AND DEVELOPMENT OF THE SHORT MEASURE)

6.1 INTRODUCTION

This chapter leads into item reduction stage and presents the findings in relation to the second objective of the study outlined in chapter 4.

The objective of the study was to develop a short measure employing multicollinearity factor analysis, regression modelling and an expert based approach to evaluate the outcomes of endodontic treatment.

6.2 STUDY RESPONSE

In this stage patient, just about to undergo specifically endodontic treatment provided by undergraduate students, who met the inclusion criteria (aged 18-64 years) were approached by the researcher and were invited to take part in the study. Overall, 106 patients attending primary dental care at King's College London Dental Institute, agreed to take part in the study, of whom 101 patients (95%) completed all the three stages of the questionnaires (pre- and post-endodontic treatment and at their one month follow-up visit).

TABLE 6.1: CHARACTERISTICS OF STUDY PARTICIPANTS OF STAGE II PARTICIPANTS IN EOM CREATION (N=101)

		Number	Percentage (%)
	Total	**101**	**100%**
Gender	Male	61	60
	Female	40	40
Age	18-24	13	13
	25-34	29	29
	35-44	27	27
	45-54	16	16
	55-64	16	16
Ethnicity	White	43	43
	Black Caribbean	22	22
	Black African	16	16
	Black other	4	4
	Indian	2	2
	Pakistani	2	2
	Chinese	1	1
	Any other ethnic group	9	9
	Don't want to mention	3	3

In order to develop a new short outcome measure for endodontic treatment based on regression analysis, the following methods were employed on the follow-up data to reduce and identify the items for the measure:

1. Collinearity.
2. Factor Analysis.
3. Regression Analysis.
4. Expert-opinion.

Each of which is reported in turn starting with collinearity:

6.3 COLLINEARITY (MULTICOLLINEARITY)

In this stage Collinearity (multicollinearity) was undertaken to identify a those items which were superfluous because of the high correlation with other items of the questionnaire. All 12 items of GOHAI were discarded because of the high correlation with 46 items derived from OHIP-49 (Table I Appendix A). Spearman correlation was used; as it gives as much information as the Pearson correlation coefficient and is of wider validity. Field (2005) has reported perfect collinearity exists when at least one variable is a perfect linear combination of the others, e.g. correlation coefficient = 1. GOHAI items had correlation greater than 0.1 so they were dropped after, consultation with a statistician as in statistical term the simplest approach would be to use only one of them, since one variable conveys essentially all the information in the other variable (Smith et al., 1995) which was evident from the initial data analysis. The OHIP-49 items were retained as OHIP-49 has been reported to be one of the most commonly used measure it is based on the conceptual model of the oral health ICIDH, and this is probably one of the reasons for its popularity, reputation and strength. The review of the core instruments in Chapter 5 also report that GOHAI is better in detecting in forms of pain and dysfunction while OHIP is better in detecting physical, psychological and social impacts of oral conditions.

6.4 FACTOR ANALYSIS

The extraction method used was Varimax rotation using Kaiser normalisation. In both cases the items that had significant loadings in significant components were taken as independent variables. Multicollinearity and interaction of the items were taken into account to make a selection of items as well as their contribution to the R-square of the model. The computer packages SPSS-15 and SAS were used in this analysis. Scree plots were used to visualise which dimensions were the most important.

Table 6.4 shows the results of the factor analysis and Figure 6.4 shows the Scree plot. In Table 6.4 six factors explained 60% of the total variability in the data. The first factor explained 47% of the variance, the second 7%, the third 6%, the fourth 4% and the fifth and sixth 3%. In total six factors explained 60% of the variation. As shown in Table 6.4, the factorial structure was satisfactory with a loading of >0.40 on each subscale for all items.

TABLE 6.4: EXPLORATORY FACTOR ANALYSIS OF ENDODONTIC OUTCOME MEASURE ITEMS (N=101)

Conceptual dimension + items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
Functional						
Difficulty chewing		0.80				
Trouble pronouncing word				0.58		
Tooth doesn't look right	0.42					
Appearance affected	0.73					
Breath has been stale	0.60					
Sense of taste worsened	0.44					
Food catching		0.54				
Digestion worsened						
Physical Pain						
Painful aching in mouth		0.58				
Sore jaw		0.40				
Headache's					0.56	
Sensitive teeth		0.72				
Toothache					0.49	
Painful gums						
Uncomfortable to eat		0.67				
Sore spots in mouth		0.53				
Psychological Discomfort						
Worried by dental problems						
Self- conscious	0.69					
Miserable	0.51					
Appearance	0.86					
Tense	0.57					
Physical Disability						
Speech unclear	0.42			0.71		
People misunderstood some of the words				0.79		
Less flavour in food				0.57		
Unable to brush properly		0.51				
Avoid eating food		0.68				
Diet unsatisfactory		0.51				
Avoided smiling	0.83					
Interrupted meals		0.59				
Psychological Disability						
Interrupted sleep					0.67	
Upset	0.45					
Difficult to relax	0.44		0.48			
Felt depressed	0.62					
Concentration affected	0.46					
Bit embarrassed	0.84					
Social Disability						
Avoid going out	0.61		0.40			
Less tolerant of others			0.71			
Trouble getting along			0.93			
Bit irritable with other			0.68			
Difficulty in doing usual jobs			0.46			
Handicap						
General health worsened			0.45			
Financial loss						0.55
Unable to work to full capacity	0.45		0.41			

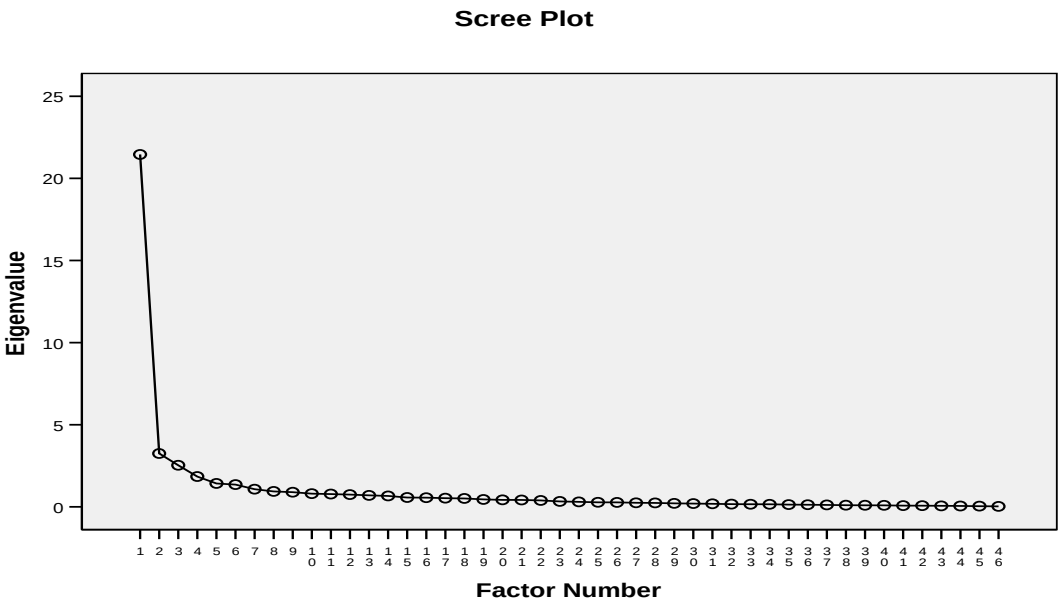

FIGURE 6.4: SCREE PLOT OF THE FACTOR ANALYSIS OF ENDODONTIC OUTCOME MEASURE ITEMS

The scree plot above (Figure 6.4) presents the eigenvalues of each factor in descending order, and helps determine where there is a rapid drop in the proportion of variance explained. In this case, the scree plot suggested a model of up to six factors.

6.5 REGRESSION ANALYSIS

In this next step regression analysis was undertaken. Least-squares step was done in two stages: first, regression with the aggregate for each dimension as the dependent variable (Table 6.5) and second, with the aggregate total score as dependent variable (Table 6.5.1). In both cases the items that had significant loadings in significant components were taken as independent variables.

In the first stage of the least-squares estimation, taking one dimension at a time as dependent variables, we arrived at a version of the questionnaire with a total of 22 items

(Table 6.5), of which five are for functional, four for physical pain, two for psychological discomfort, three for physical disability, three for psychological disability, three for social disability and two for handicap. These regressions are shown in Tables 6.5. When the total aggregate score for the OHIP was taken as the dependent variable, the following variables were found to be either multi-collinear or non-significant in the model: difficulty in chewing (P=0.81), breath has been stale (P=0.36); miserable with (P=0.13); financial loss (P=0.41); appearance with (P=0.55); irritable with other (P=0.74) and trouble getting along with other (P=0.38). The final regression model, with a total 15 items retained after this second step is presented in Table 6.5.1. This is to define the short version of the health outcome measure for endodontic treatment.

6.6 EXPERT OPINION

Twelve clinicians involved in supervising undergraduate students treating patients in primary dental care department were consulted to make general suggestions for changes or to include any new items. The 15 items defined were carefully analysed by the clinicians, together with excluded items and one item ‘worried’ was added to the final questionnaire by an expert based approach to encompass all the seven domains of OHIP-49. The items relevance to endodontic and also whether or not the item corresponds to the domain (subscale) assigned was discussed in detail. Agreement was reached over 80% on all items drafted from analysis of data and one new item “worried” was added to the questionnaire.

TABLE 6.5: LINEAR REGRESSION MODEL BY TAKING ONE DIMENSION AT A TIME AS DEPENDENT VARIABLES FOR EACH OHIP DIMENSION IN THE DEVELOPMENT OF OHIP- EOM (N=101)

Conceptual dimension and items	Unstandardized coefficients	sig	95% confidante interval for B	
	B		Lower bound	Upper bound
Functional Limitation				
Difficulty chewing	0.986	.000	0.606	1.366
Trouble pronouncing word	1.987	.000	1.502	2.471
Sense of taste worsened	1.495	.000	1.065	1.925
Food catching	1.645	.000	1.179	2.111
Breath has been stale	1.824	.000	2.215	2.215
Physical pain				
Uncomfortable to eat	1.845	.000	1.428	2.262
Sore jaw	2.425	.000	2.053	2.797
Sensitive teeth	1.341	.000	1.428	1.743
Toothache	1.585	.000	1.117	2.053
Psychological discomfort				
Miserable	2.876	.000	1.500	4.252
Tense	2.357	.004	0.785	3.930
Physical disability				
Unable to brush properly	1.652	.000	1.024	2.280
Avoid eating some foods	2.281	.000	2.244	3.398
Interrupted sleep	2.237	.000	1.909	2.566
Misunderstood some of the words	3.638	.000	2.035	5.240
Psychological disability				
Felt depressed	2.364	.000	1.971	2.757
Bit embarrassed	1.358	.000	1.909	1.707
Social disability				
Less tolerant of your family	2.933	.017	0.555	5.430
Avoid going out	2.654	.038	0.152	5.155
Getting along with other people	3.985		1.731	6.239
Handicap				
General health worsened	4.221	.001	0.769	7.672
Unable to work to fill capacity	6.755	.017	4.625	8.886

TABLE: 6.5.1 LINEAR REGRESSION MODEL BY TAKING THE TOTAL AGGREGATE SCORE FOR THE OHIP AS THE DEPENDENT VARIABLE (N=101)

Conceptual dimension and items	Unstandardized coefficients	sig	95% confidante interval for B	
	B		Lower bound	Upper bound
Functional Limitation				
Trouble pronouncing word	2.548	.001	1.015	4.081
Sense of taste worsened	3.951	.000	2.437	5.464
Food catching	2.044	.002	0.782	3.305
Physical Pain				
Painful aching in mouth	2.035	.005	0.619	3.451
Sore jaw	2.585	.000	1.341	3.829
Sensitive teeth	2.331	.001	0.999	3.664
Toothache	2.446	.003	0.828	4.064
Psychological Discomfort				
Worried	*	*	*	*
Physical disability				
Unable to brush properly	1.384	.037	0.088	2.681
Avoid eating some foods	3.041	.000	1.548	4.534
Interrupted sleep	2.578	.001	1.077	4.079
Psychological Disability				
Felt depressed	4.048	.000	2.480	5.615
Bit embarrassed	5.713	.000	4.304	7.122
Social disability				
Less tolerant of your family	4.494	.000	2.536	6.453
Handicap				
General health worsened	3.574	.000	1.883	5.265
Unable to work to fill capacity	4.546	.000	2.810	6.283

Note: Worried was added to the measure by an expert opinion.

The self-oral health rating measure showed high correlation with preliminary results of the measure which is further validated in stage III of the results. Global transition judgment scores reported improvement in quality of life of patients 28% o reported “improved a lot” after completion of treatment and subsequently 44% reported “improved a lot” at follow-up visit. The questionnaire also included VAS for pain. Preliminary results showed very few responses to those questions as patients were not in pain at that point in time.

6.6 SUMMARY

After addressing overlap between items through assessing multicollinearity, factor analysis, regression analysis and expert based approach were all used in this stage to reduce the test instrument, derived from existing measures from 58 items to a new 16-item endodontic outcome measure (EOM), thus addressing the objective of this stage of the research.

The next chapter (Testing stage) describes testing and validation of the instrument on a new group of patients in the same primary dental care setting.

CHAPTER 7 STAGE III THE FINAL INSTRUMENT (TESTING STAGE)

7.1 INTRODUCTION

This final chapter of the results outlines the findings of the testing stage and thus addresses the third objective of the study outlined in chapter 4. The results presented outlines the findings of the evaluation of the Endodontic Outcome Measure (EOM) which was tested on adult patients attending primary dental care at King's College Dental Hospital specifically for endodontic treatment provided by undergraduate students. Each of the aspects of the evaluation will be addressed in turn, starting with an overview of the respondents**.**

7.2 SUBJECTS IN STAGE III

A total of 57 adult patients presenting for root canal treatment at Kings College London dental Institute were invited to take part in the study. Among those invited, 55 met the (18-64 years) inclusion criteria but only 30 completed the questionnaires both at the beginning and the end of the treatment (response rate 53%).

The socio-demographic and other characteristics of the thirty respondents are presented in (Table 7.2). Overall, there was a balance between males and females a spread across adult age-bands, with 25-34 age-bands being the mode.

TABLE 7.2: SOCIO-DEMOGRAPHIC CHARACTERISTICS OF CLINICAL STUDY GROUP (N=30)

		N	%
Total		**30**	**100**
Gender	Male	15	50
	Female	15	50
Age	18-24	8	27
	25-34	9	30
	35-44	5	17
	45-54	3	10
	55-64	5	17
Ethnicity	White	13	43
	Black Caribbean	7	23
	Black African	4	13
	Black other	1	03
	Chinese	2	07
	Any other ethnic group	2	07
	Don't wish to mention	1	03

7.3 PREVALENCE AND SCORE FOR EACH DIMENSION OF THE OUTCOME MEASURE

The following table 7.3 shows all the items of the developed questionnaire based on regression analysis and expert based approach. Column one and two shows the prevalence of each item pre and post treatment respectively. The prevalence of the 16 items questions ranged from 87% (Q3) to 20% (Q15) pre-operatively and 53% (Q3) to 0 % (Q5) post-operatively. The severity item mean of each item both pre and post operatively is shown in column four and five. Severity ranged from 2.76 (Q3) to 0.73 (Q15) pre-operatively to 1.63 (Q3) to 0.30 (Q5) post-operatively.

TABLE 7.3: PREVALENCE AND SEVERITY ITEM MEAN OF EACH ITEM (N=30)

	Prevalence: % reporting item occasionally, fairly often or very often	Prevalence: % reporting item occasionally, fairly often or very often	Severity: item mean (0-4)	Severity: item mean (0-4)
Conceptual dimension and item	**Pre treatment**	**Post treatment**	**Pre treatment**	**Post treatment**
Functional limitation				
Trouble pronouncing any words	30.00	17.00	0.86	0.56
Sense of taste worsened	23.00	10.00	0.76	0.46
Food catching	87.00	53.00	2.76	1.63
Physical pain				
Painful aching in mouth	60.00	17.00	1.93	0.93
Sore jaw	33.00	0.00	1.00	0.30
Sensitive teeth	73.00	27.00	2.20	1.10
Toothache	80.00	10.00	2.20	0.93
Psychological discomfort				
Worried	70.00	27.00	1.96	1.10
Physical disability				
Unable to brush properly	27.00	10.00	1.00	0.53
Avoid eating some food	63.00	33.00	2.00	1.16
Interrupted sleep	60.00	23.00	1.63	0.93
Psychological disability				
Depressed	57.00	33.00	1.63	1.06
Bit embarrassed	53.00	30.00	1.60	0.96
Social disability				
Less tolerant of your partner and family	33.00	10.00	0.96	0.46
Handicap				
General health worsened	20.00	7.00	0.73	0.46
Unable to work to full capacity	27.00	10.00	0.93	0.60

7.4 RELIABILITY OF THE MEASURE (95% CONFIDENCE INTERVAL OF EACH ITEM OF THE OUTCOME MEASURE)

Table 7.4 below shows following table shows the 95% confidence interval of each item both at the pre and post treatment levels which is statistically significant which suggests usefulness of the intervention endodontic treatment.

TABLE: 7.4 95% CONFIDENCE INTERVAL OF EACH ITEM (N=30)

	95% Confidence Interval	95% Confidence Interval
Conceptual dimension and items	**Pre treatment**	**Post Treatment**
Functional limitation		
Trouble pronouncing any words	(0.38;1.34)	(0.24;0.88)
Sense of taste worsened	(0.34;1.19)	(0.21;0.72)
Food catching	(2.36;3.16)	(1.34;1.91)
Physical pain		
Painful aching in mouth	(1.45;1.93)	(0.65;1.20)
Sore jaw	(0.58;1.00)	(0.12;0.47)
Sensitive teeth	(1.75;2.20)	(0.81;1.38)
Toothache	(1.80;2.20)	(0.69;1.17)
Psychological discomfort		
Worried	(1.51;2.42)	(0.75;1.44)
Physical disability		
Unable to brush properly	(0.58;1.41)	(0.27;0.78)
Avoid eating some food	(1.47;2.52)	(0.84;1.49)
Interrupted sleep	(1.23;1.63)	(0.65;1.20)
Psychological disability		
Depressed	(1.08;2.18)	(0.66;1.47)
Bit embarrassed	(1.09;1.60)	(0.58;1.35)
Social disability		
Less tolerant of your partner and family	(0.53;0.96)	(0.21;0.72)
Handicap		
General health worsened	(0.38;0.73)	(0.23;0.70)
Unable to work to full capacity	(0.54;0.93)	(0.34;0.85)

TABLE: 7.4.1 95% CONFIDENCE INTERVAL AT INSTRUMENT LEVEL (N=30)

	Pre-treatment			Post-treatment		
Domains	**Range**	**Mean**	**95% CI**	**Range**	**Mean**	**95% CI**
Functional limitation	1-9	4.4	(3.5,5.3)	1-7	2.6	(2.1,3.2)
Physical pain	0-15	7.3	(6.0,8.6)	0-8	3.2	(2.5,3.9)
Psychological discomfort	0-4	2.0	(1.5,2.4)	0-3	1.1	(0.75,1.4)
Physical disability	0-11	4.6	(3.4,5.8)	0-6	2.6	(1.9,3.4)
Psychological disability	0-8	3.2	(2.3,4.1)	0-6	2.0	(1.3,2.7)
Social disability	0-4	1.0	(0.53,1.4)	0-2	0.47	(0.21,0.72)
Handicap	0-6	1.6	(1.05,2.8)	0-3	1.06	(0.68,1.4)

Reliability coefficients can be reported with 95% CIs by statistical software to evaluate the internal consistency of respondent scores on questionnaire items. 95% CIs were compared to detect different effects between groups according to the two data sets before and after endodontic treatment.

7.5 RESPONSIVENESS: (CHANGE IN TIME)

Each dimension of the instrument is explored in turn to examine its responsiveness, starting with self-rating of oral health, and finishing with the global transition judgement, with each of the sixteen items addressed in turn. It is more informative from conceptual and psychometric prospective to report scores on item-by-item basis. Aggregate scores tend to provide little information about individual differences in QoL (Osoba, 1994; Bush et al., 1995, 2000; Gill and Feinstein 1995; Haberman, 1995). Haberman (1995) has also discussed that clinicians don't plan their interventions based on aggregate scores of QoL because they are difficult to interpret and fail to provide any information about patient's state in different domains. Asking patients to rate each item or domain is particularly helpful for clinicians but is a cumbersome scoring system for researchers.

7.5.1 SELF-RATING OF ORAL HEALTH

Figure 7.5.1 and Table 7.5.1 below show visible difference between pre and post treatment level for 'Self-rating of oral health, as none of the participants reported poor oral health after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =20.0; P-value=0.00).

FIGURE 7.5.1: SELF-RATING OF ORAL HEALTH

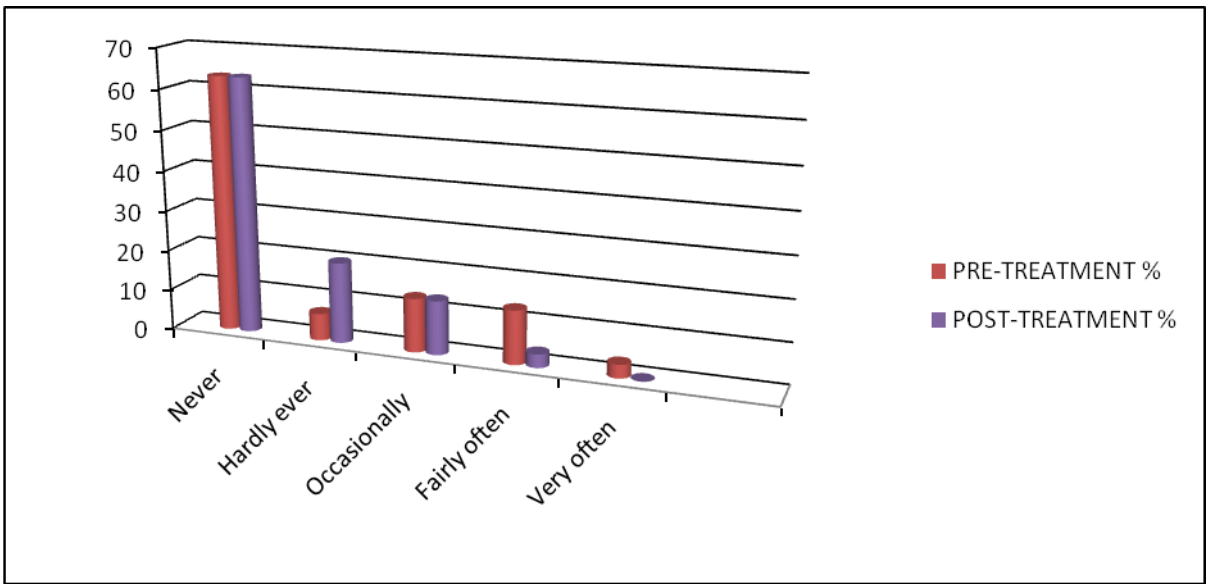

TABLE 7.5.1: SELF-RATING OF ORAL HEALTH (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Excellent	2	6.7	2	6.7
Very good	4	13.3	9	30.0
Good	8	26.7	14	46.7
Fair	11	36.7	5	16.7
Poor	5	16.7	0	0.00
Total (n)	30	100.0	30	100.0

7.5.2 TROUBLE PRONOUNCING ANY WORD

Figure 7.5.2 and Table 7.5.2 below show visible difference between pre and post treatment level as none of the participants reported a problem in 'pronouncing any word' at 'very often' level, after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =9.0; P-value=0.003).

FIGURE 7.5.2: TROUBLE PRONOUNCING ANY WORD

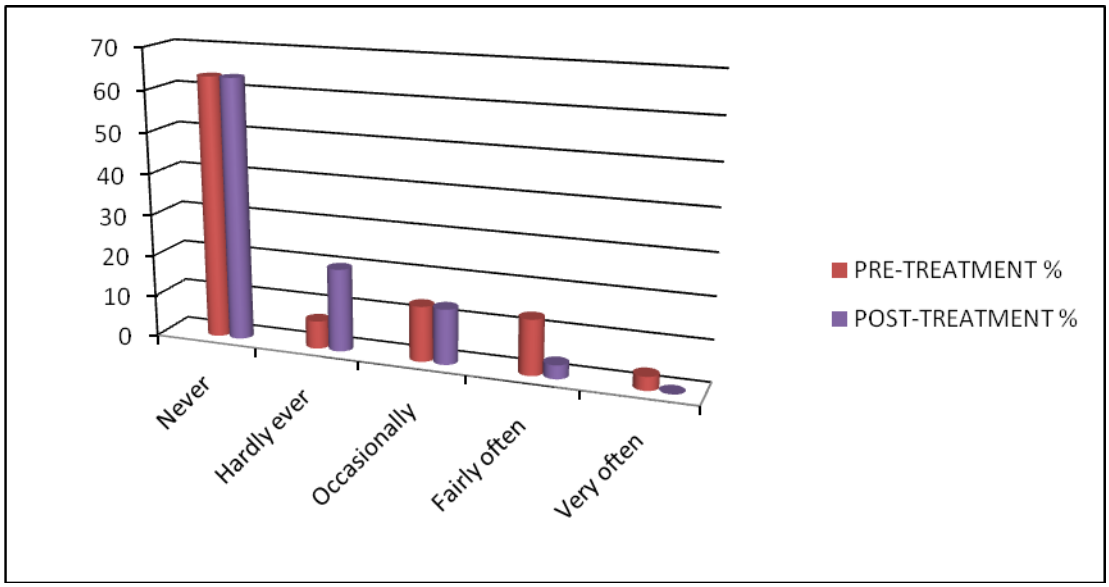

TABLE 7.5.2: TROUBLE PRONOUNCING ANY WORDS (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	19	63.3	19	63.3
Hardly ever	2	6.7	6	20.0
Occasionally	4	13.3	4	13.3
Fairly often	4	13.3	1	3.3
Very often	1	3.3	0	0
Total (n)	30	100.0	30	100.0

7.5.3 SENSE OF TASTE WORSENED

Figure 7.5.3 and Table 7.5.3 below show visible difference between pre and post treatment level as none of the participants reported a problem in 'sense of taste worsened' at 'very often' level, after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =8.0; P-value=0.005).

FIGURE 7.5.3: SENSE OF TASTE WORSENED

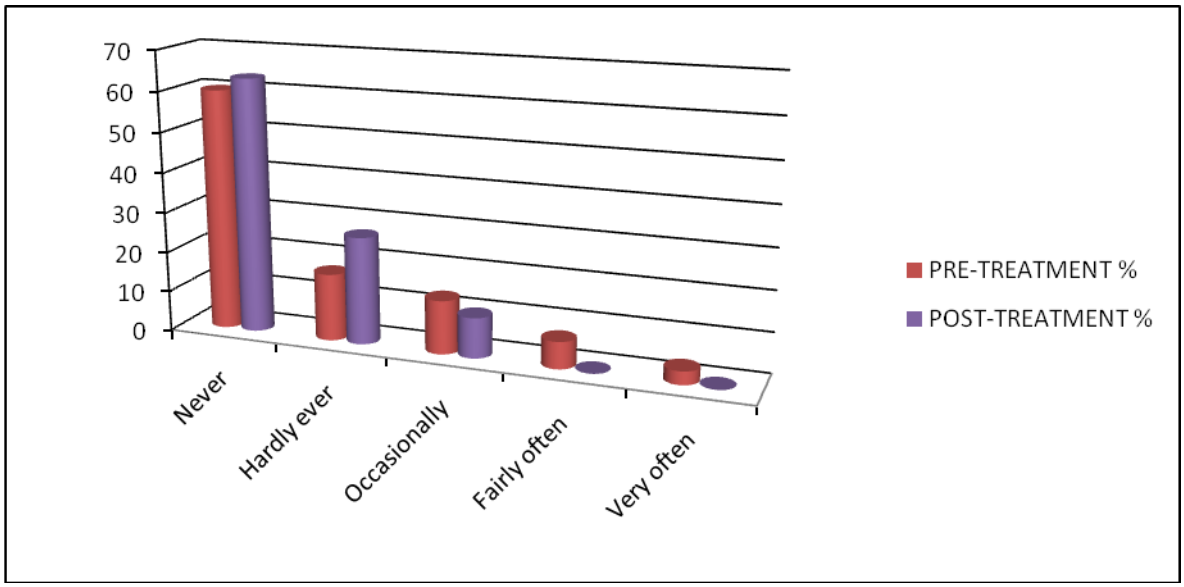

TABLE 7.5.3: SENSE OF TASTE WORSENED (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	18	60.0	19	63.3
Hardly ever	5	16.7	8	26.7
Occasionally	4	13.3	3	10.0
Fairly often	2	6.7	0	0
Very often	1	3.3	0	0
Total (n)	30	100.0	30	100.0

7.5.4 FOOD CATCHING

Figure 7.5.4 and Table 7.5.4 below show visible difference between pre and post treatment level as none of the participants reported a 'food catching problem' at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =26.0; P-value=0.000).

FIGURE 7.5.4: FOOD CATCHING

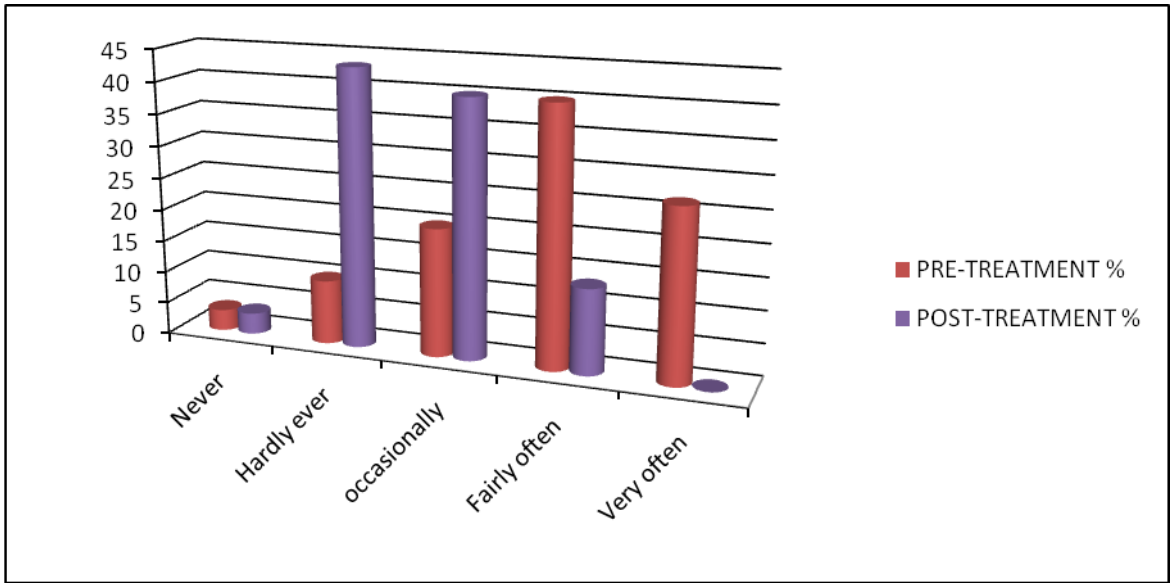

TABLE 7.5.4: FOOD CATCHING (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	1	3.3	1	3.3
Hardly ever	3	10.0	13	43.3
occasionally	6	20.0	12	40.0
Fairly often	12	40.0	4	13.3
Very often	8	26.7	0	0.00
Total (n)	30	100.0	30	100

7.5.5 PAINFUL ACHING IN THE MOUTH

Figure 7.5.5 and Table 7.5.5 below show visible difference between pre and post treatment level as none of the participants reported a 'painful aching problem' at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =22.0; P-value=0.000).

FIGURE 7.5.5: PAINFUL ACHING IN THE MOUTH

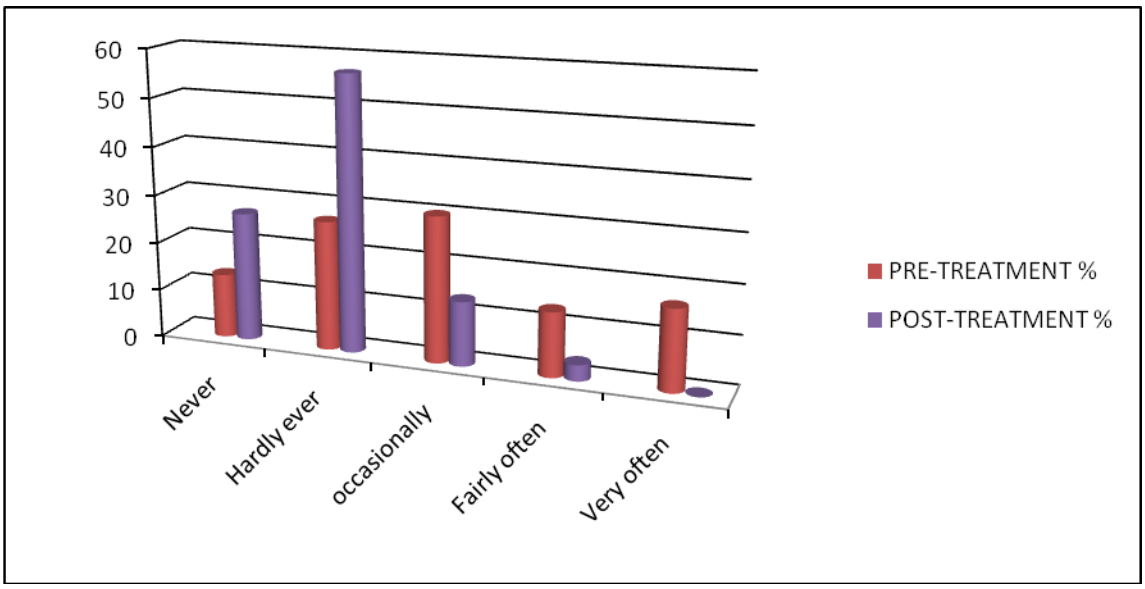

TABLE 7.5.5: PAINFUL ACHING IN THE MOUTH (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	4	13.3	8	26.7
Hardly ever	8	26.7	17	56.7
occasionally	9	30.0	4	13.3
Fairly often	4	13.3	1	3.3
Very often	5	16.7	0	0
Total (n)	30	100.0	30	100.0

7.5.6 SORE JAW

Fig 7.5.6 and Table 7.5.6 below show visible difference between pre and post treatment level as none of the participants reported a 'sore jaw problem at 'occasionally/ fairly/ very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =14.0; P-value=0.000).

FIGURE 7.5.6: SORE JAW

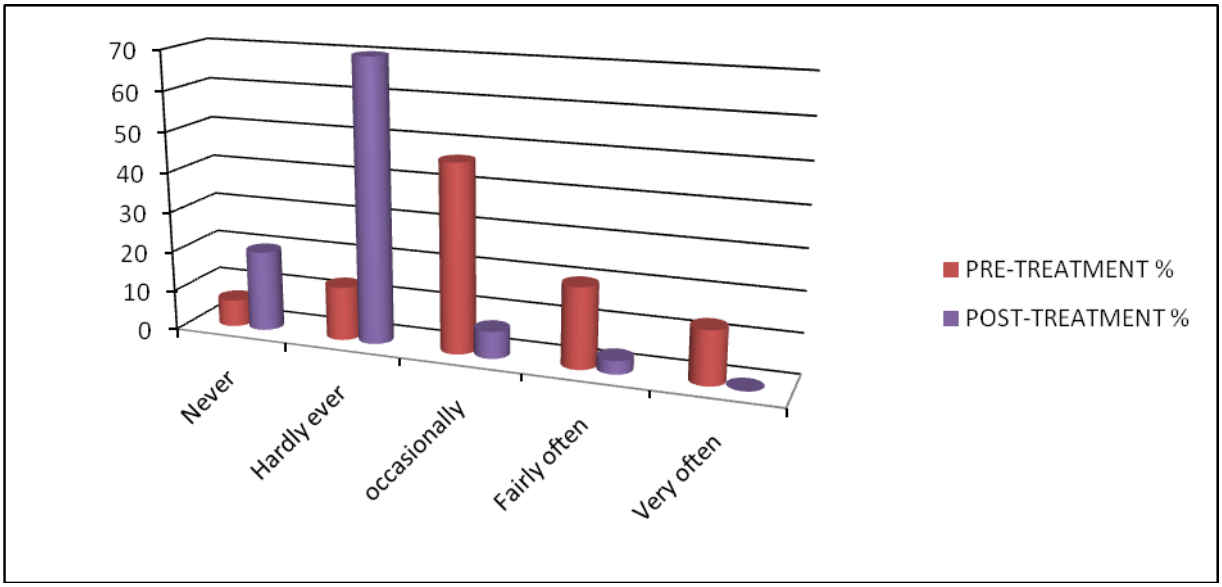

TABLE 7.5.6: SORE JAW (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	14	46.7	21	70.0
Hardly ever	6	20.0	9	30.0
occasionally	6	20.0	0	0.0
Fairly often	4	13.3	0	0.0
Very often	0	0.0	0	0.0
Total (n)	30	100.0	30	100.0

7.5.7 SENSITIVE TEETH

Figure 7.5.7 and Table 7.5.7 below show visible difference between pre and post treatment level in 'sensitive teeth' as none of the participants reported 'sensitivity problem' at 'occasionally/ fairly/ very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =24.0; P-value=0.000).

FIGURE 7.5.7: SENSITIVE TEETH

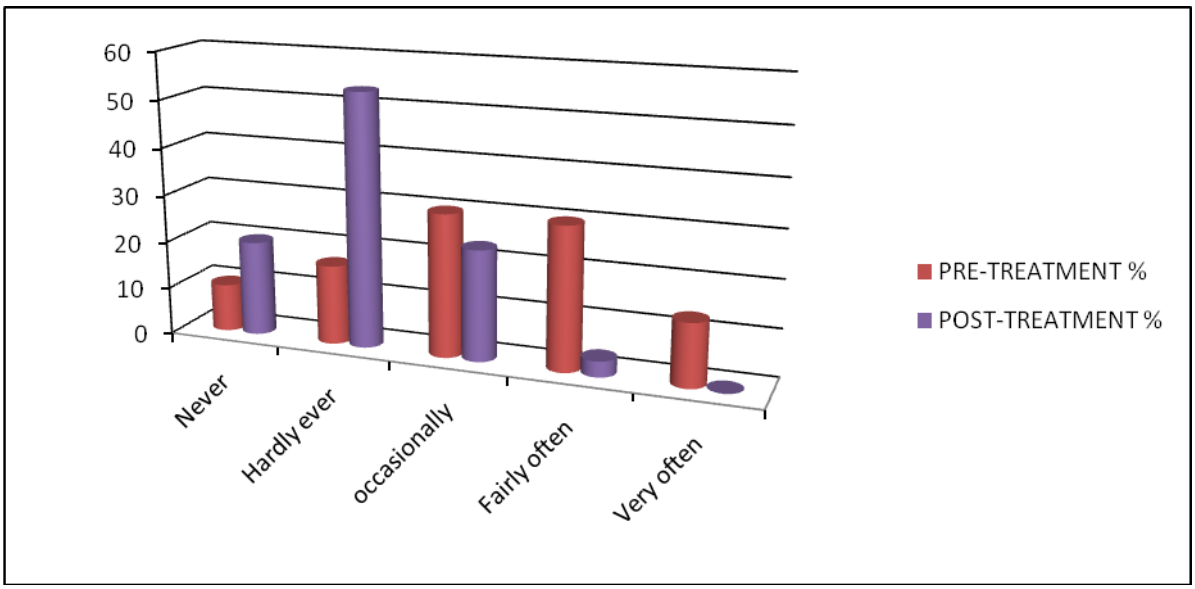

TABLE 7.5.7: SENSITIVE TEETH (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	3	10.0	6	20.0
Hardly ever	5	16.7	16	53.3
occasionally	9	30.0	7	23.3
Fairly often	9	30.0	1	3.3
Very often	4	13.3	0	0.0
Total (n)	30	100.0	30	100

7.5.8 TOOTH ACHE

Fig 7.5.8 and Table 7.5.8 below show visible difference between pre and post treatment level for 'toothache' as none of the participants reported a 'tooth ache problem' at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =26.0; P-value=0.000).

FIGURE 7.5.8: TOOTHACHE

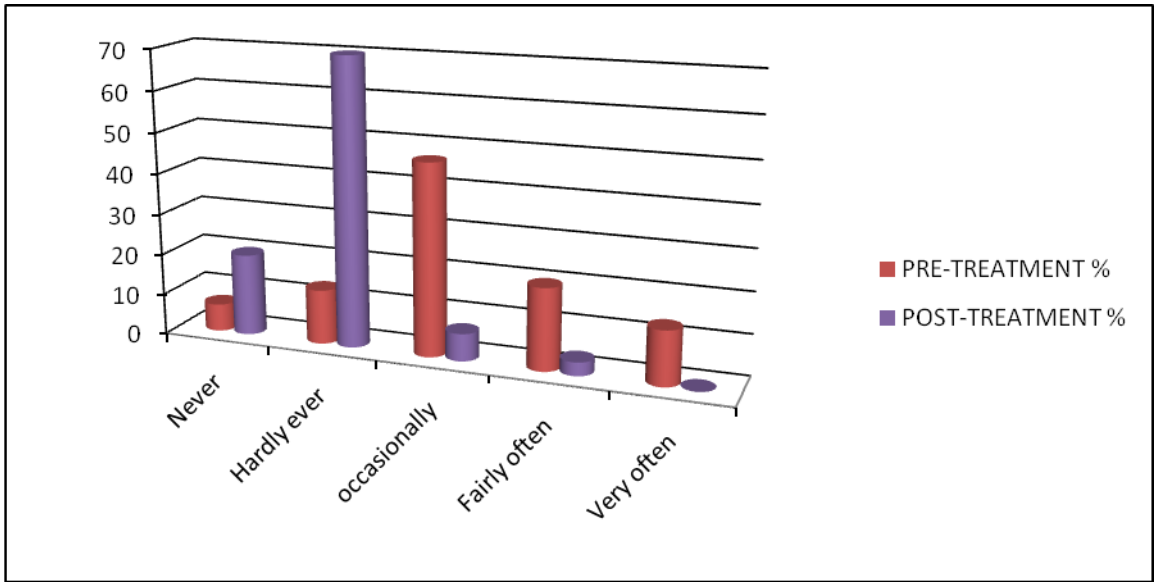

TABLE 7.5.8: TOOTH ACHE (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	2	6.7	6	20.0
Hardly ever	4	13.3	21	70.0
occasionally	14	46.7	2	6.7
Fairly often	6	20.0	1	3.3
Very often	4	13.3	0	0.0
Total (n)	30	100.0	30	100

7.5.9 UNABLE TO BRUSH PROPERLY

Figure 7.5.9 and Table 7.5.9 below show visible difference between pre and post treatment level as none of the participants reported 'unable to brush properly' at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =12.0; P-value=0.000).

FIGURE 7.5.9: UNABLE TO BRUSH PROPERLY

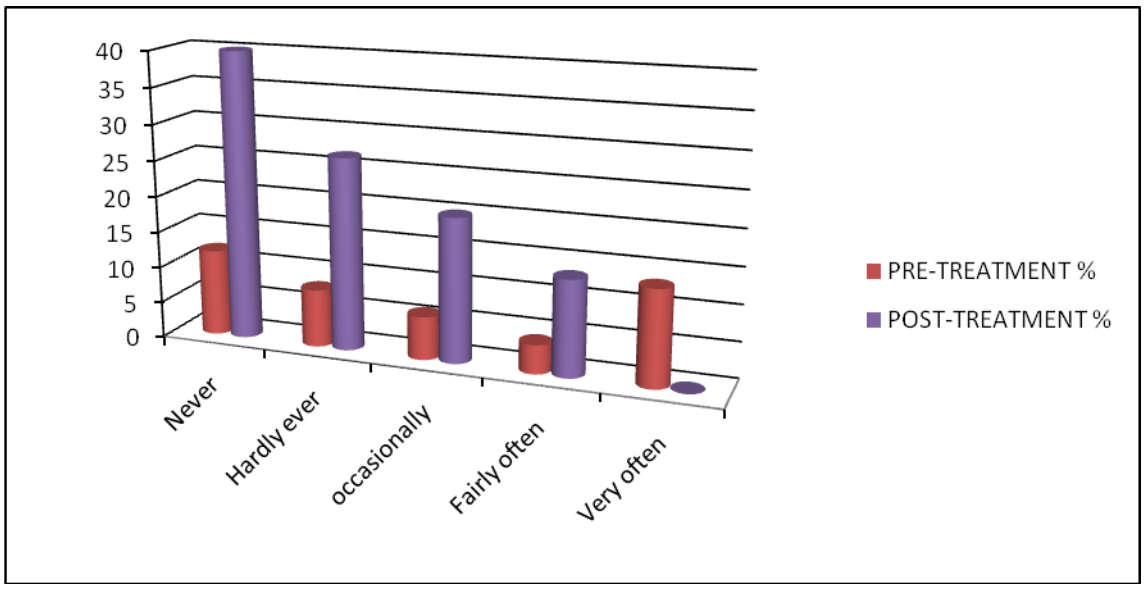

TABLE 7.5.9: UNABLE TO BRUSH PROPERLY (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	12	40.0	17	56.7
Hardly ever	10	33.3	10	33.3
occasionally	6	20.0	3	10.0
Fairly often	0	0.0	0	0.0
Very often	2	6.7	0	0.0
Total (n)	30	100	30	100

7.5.10 AVOID EATING SOME FOOD

Figure 7.5.10 and Table 7.5.10 below show visible difference between pre and post treatment level as none of the participants reported 'avoiding eating some food' problem at 'very often level' after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =18.0; P-value=0.000).

FIGURE 7.5.10: AVOID EATING SOME FOOD

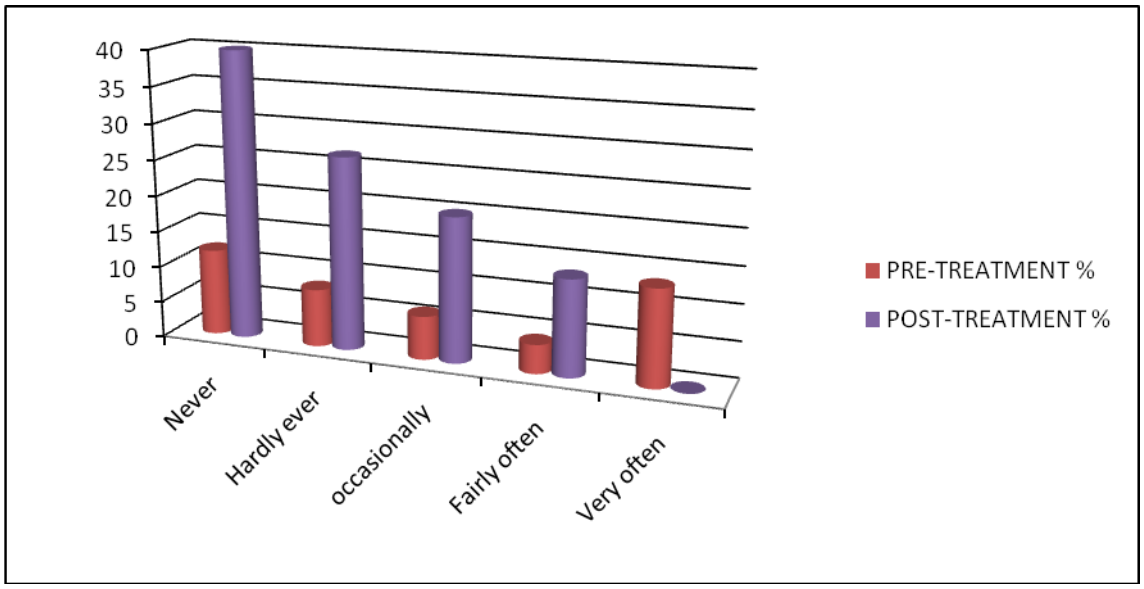

TABLE 7.5.10: AVOID EATING SOME FOOD (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	6	20.0	7	23.3
Hardly ever	5	16.7	13	43.3
occasionally	8	26.7	8	26.7
Fairly often	5	16.7	2	6.7
Very often	6	20.0	0	0.0
Total (n)	30	100.0	30	100.0

7.5.11 INTERRUPTED SLEEP

Figure 7.5.11 and Tab 7.5.11 below show visible difference between pre and post treatment level as none of the participants reported 'interrupted sleep' problem at 'fairly/ very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =18.0; P-value=0.000).

FIGURE 7.5.11: INTERRUPTED SLEEP

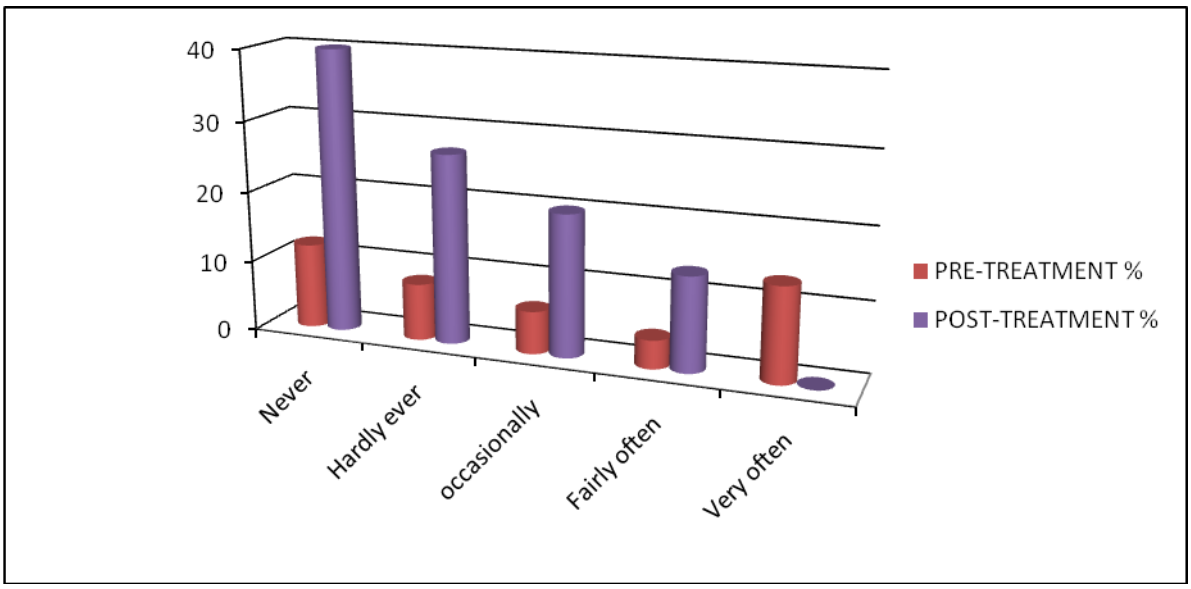

TABLE 7.5.11: INTERRUPTED SLEEP (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	5	16.7	9	30.0
Hardly ever	7	23.3	14	46.7
occasionally	14	46.7	7	23.3
Fairly often	2	6.7	0	0.0
Very often	2	6.7	0	0.0
Total (n)	30	100.0	30	100

7.5.12 WORRIED BY DENTAL PROBLEMS

Figure 7.5.12 and Table 7.5.12 below show visible difference between pre and post treatment level as none of the participants reported 'worried by dental problems' at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =22.0; P-value=0.000).

FIGURE 7.5.12: WORRIED BY DENTAL PROBLEMS

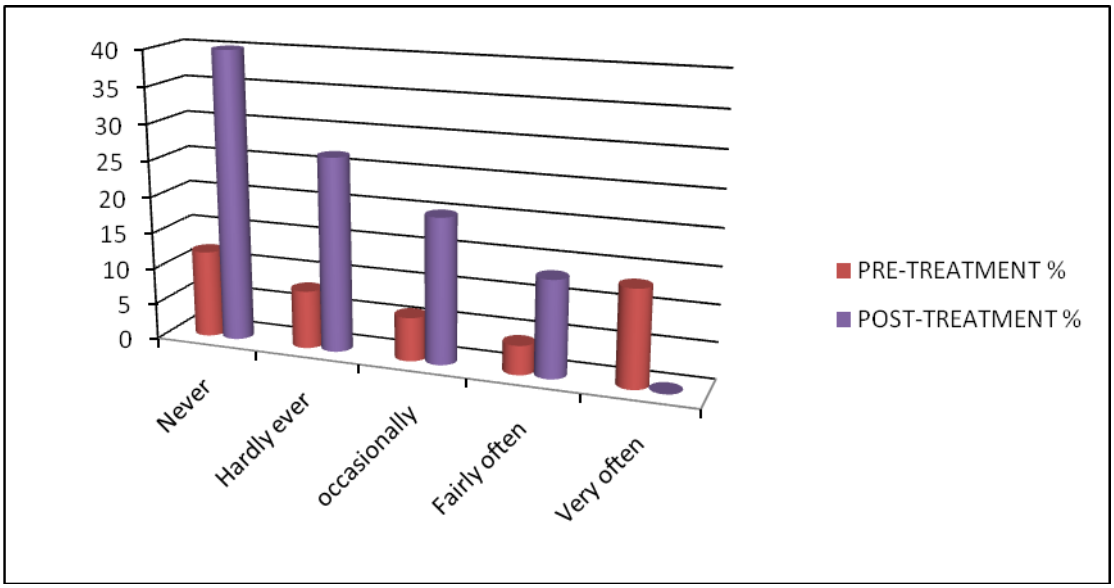

TABLE 7.5.12: WORRIED BY DENTAL PROBLEMS (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	5	16.7	8	26.7
Hardly ever	4	13.3	14	46.7
occasionally	11	36.7	5	16.7
Fairly often	7	23.3	3	10.0
Very often	3	10.0	0	0
Total (n)	30	100.0	30	100

7.5.13 FELT DEPRESSED

Figure 7.5.13 and Table 7.5.13 below show visible difference between pre and post treatment level as none of the participants reported 'felt depressed problem' at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =17.0; P-value=0.000).

FIGURE 7.5.13: FELT DEPRESSED

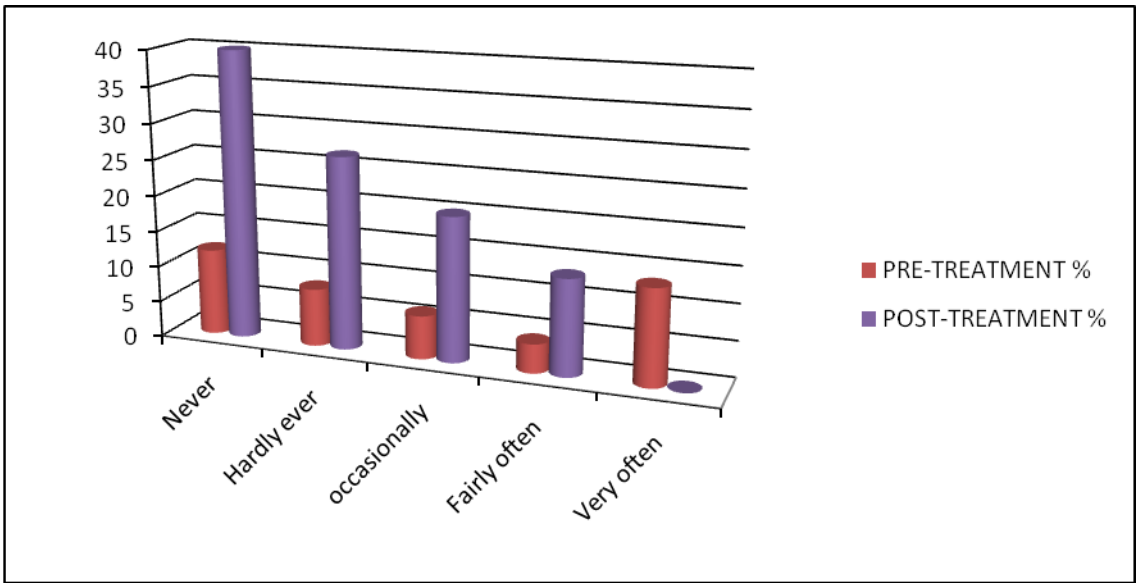

TABLE 7.5.13: FELT DEPRESSED (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	11	12	12	40.0
Hardly ever	2	8	8	26.7
occasionally	8	6	6	20.0
Fairly often	5	4	4	13.3
Very often	4	13.3	0	0.0
Total (n)	30	100.0	30	100

7.5.14 BIT EMBARRASSED

Figure 7.5.14 and Table 7.5.14 below show visible difference between pre and post treatment level as none of the participants reported 'bit embarrassed' problem at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =18.0; P-value=0.000).

FIGURE 7.5.14: BIT EMBARRASSED

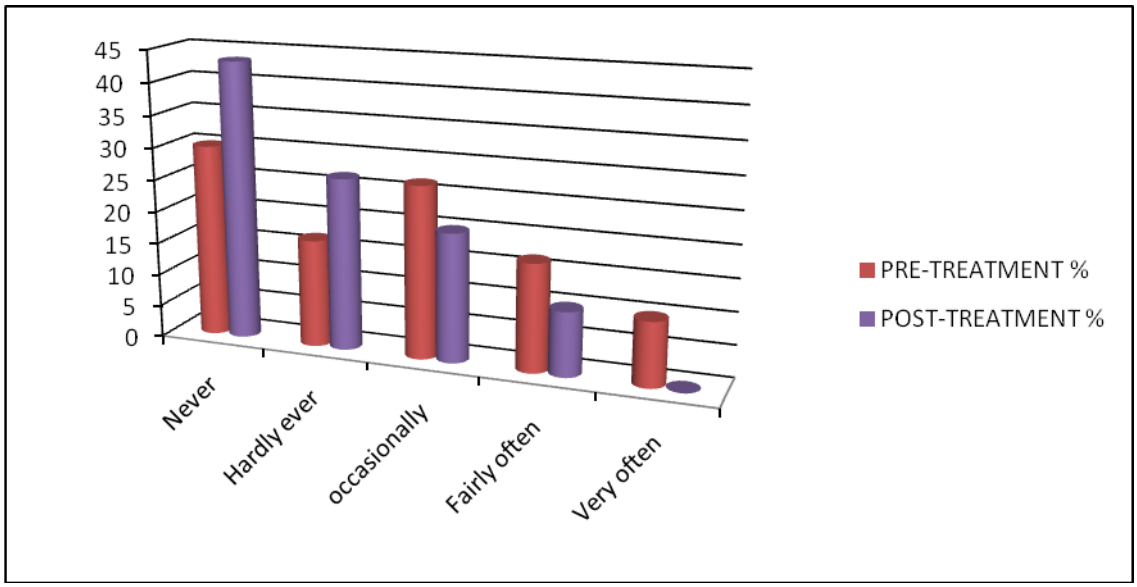

TABLE 7.5.14: BIT EMBARRASSED (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	9	30.0	13	43.3
Hardly ever	5	16.7	8	26.7
occasionally	8	26.7	6	20.0
Fairly often	5	16.7	3	10.0
Very often	3	10.0	0	0.0
Total (n)	30	100.0	30	100

7.5.15 LESS TOLERANT OF YOUR FAMILY OR PARTNER

Figure 7.5.15 and Table 7.5.15 below show visible difference between pre and post treatment level as none of the participants reported 'less tolerant of your family and partner' problem at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =12.0; P-value=0.001).

FIGURE 7.5.15: LESS TOLERANT OF YOUR FAMILY OR PARTNER

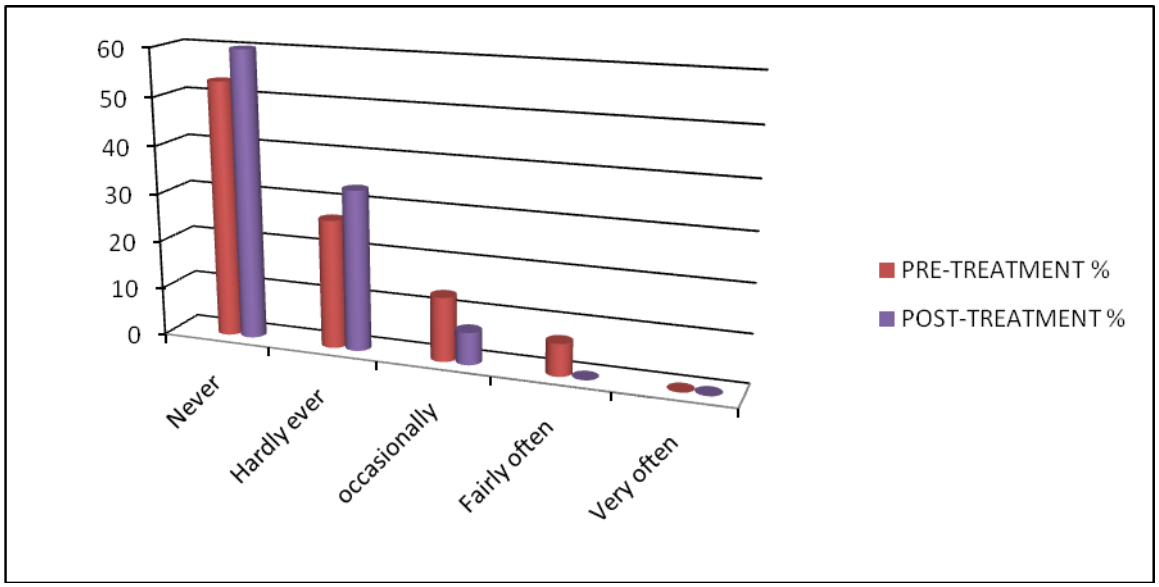

TABLE 7.5.15: LESS TOLERANT OF YOUR FAMILY OR PARTNER (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	15	50.0	19	63.3
Hardly ever	5	16.7	8	26.7
occasionally	7	23.3	3	10.0
Fairly often	2	6.7	0	0.0
Very often	1	3.3	0	0.0
Total (n)	30	100.0	30	100

7.5.16 GENERAL HEALTH WORSENED

Figure 7.5.16 and Table 7.5.16 below show visible difference between pre and post treatment level as none of the participants reported 'general health worsened' problem at 'very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =6.4; P-value=0.011).

FIGURE 7.5.16: GENERAL HEALTH WORSENED

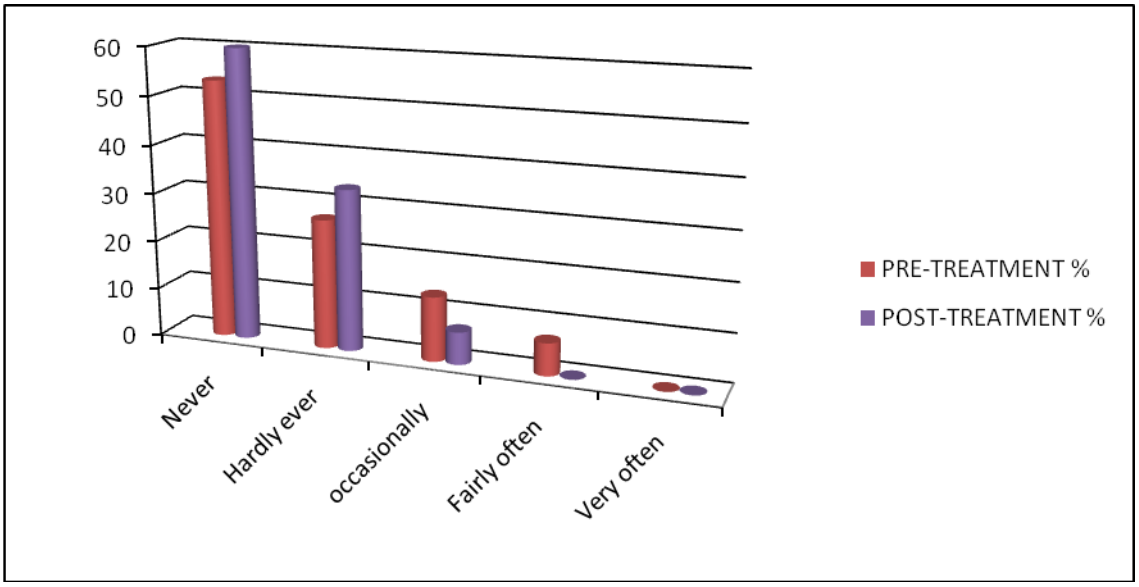

TABLE 7.5.16: GENERAL HEALTH WORSENED (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	16	53.3	18	60.0
Hardly ever	8	26.7	10	33.3
occasionally	4	13.3	2	6.7
Fairly often	2	6.7	0	0.0
Very often	0	0.0	0	0.0
Total (n)	30	100	30	100

7.5.17 UNABLE TO WORK TO FULL CAPACITY

Figure 7.5.17 and Table 7.5.17 below show visible difference between pre and post treatment level as none of the participants reported 'unable to work to full capacity' problem at 'fairly/very often' level after completion of treatment. This difference was confirmed as significant by the Friedman test (Chi-s (1df) =6.4; P-value=0.011).

FIGURE 7.5.17: UNABLE TO WORK TO FULL CAPACITY

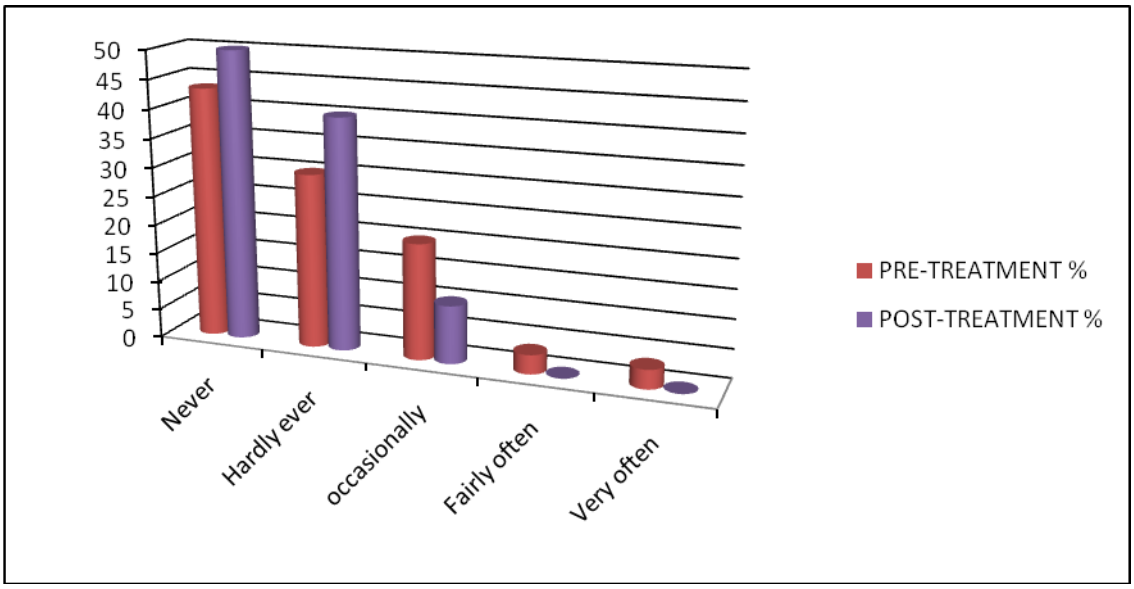

TABLE 7.5.17: UNABLE TO WORK TO FULL CAPACITY (N=30)

	PRE-TREATMENT		POST-TREATMENT	
	N	%	N	%
Never	13	43.3	15	50.0
Hardly ever	9	30.0	12	40.0
occasionally	6	20.0	3	10.0
Fairly often	1	3.3	0	0.0
Very often	1	3.3	0	0.0
Total (n)	30	100.0	30	100

7.5.18 GLOBAL TRANSITION JUDGMENT SCORES

Figure 7.5.18 and Table 7.5.18 below report (n=18) sixty percent of respondents reported 'improvement in quality of life' after completion of the endodontic treatment.

FIGURE 7.5.18: AFTER COMPLETION OF TREATMENT HAS YOUR ORAL HEALTH (GLOBAL TRANSITION JUDGMENT SCORES)

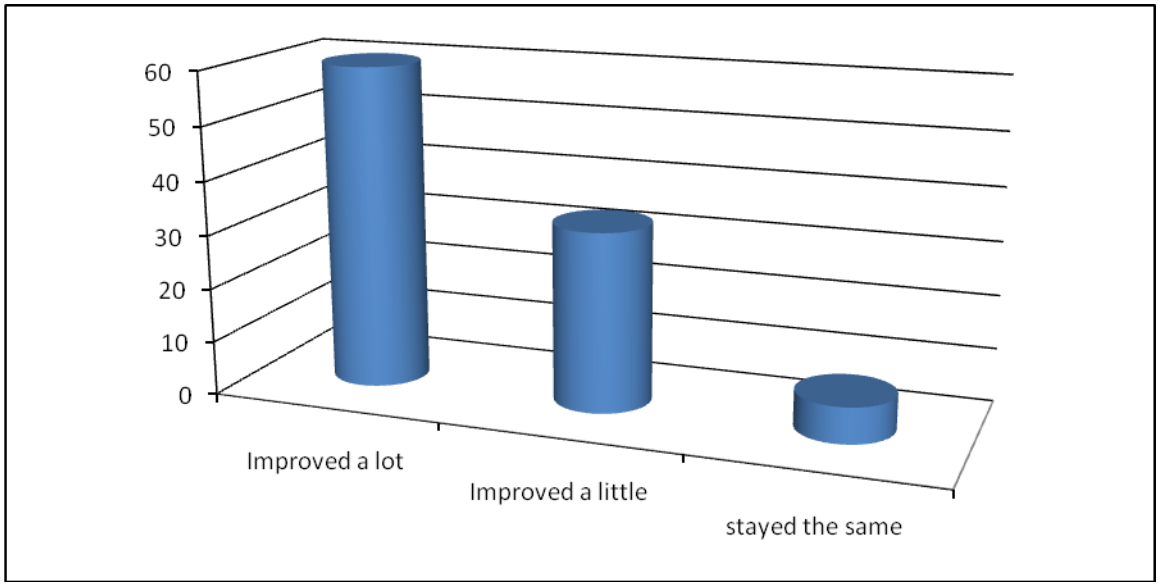

TABLE 7.5.18: AFTER COMPLETION OF TREATMENT HAS YOUR ORAL HEALTH (GLOBAL TRANSITION JUDGMENT SCORES) (N=30)

	N	%
Improved a lot	18	60.0
Improved a little	10	33.3
stayed the same	2	6.7
Total (n)	30	100.0

7.6 RESPONSIVENESS OF THE MEASURE

There was an observed gradient in the mean change of overall scores before and after treatment. The level of statistical difference across the items is also evident from the Table 7.6

TABLE 7.6: RESPONSIVENESS OF THE MEASURE (N=30)

Conceptual dimension and items	Pre treatment Mean (SD)	Post treatment Mean (SD)	P-value	Observed effect mean	Effect size (Cohen's d)
Functional limitation					
Trouble pronouncing any words	0.86(1.27)	0.56(0.85)	.002	0.30	+0.28
Sense of taste worsened	0.76 (1.13)	0.46(0.68)	.002	0.30	+0.33
Food catching	2.76(1.07)	1.63(0.76)	.000	1.13	+1.23
Physical pain					
Painful aching in mouth	1.93(1.28)	0.93(0.73)	.000	1.00	+0.99
Sore jaw	1.00(1.11)	0.30(0.46)	.001	0.70	+0.89
Sensitive teeth	2.20(1.18)	1.10(0.75)	.000	1.10	+1.14
Toothache	2.20(1.06)	0.93(0.63)	.000	1.27	+1.50
Psychological discomfort					
Worried	1.96(1.21)	1.10(0.92)	.000	0.86	+0.80
Physical disability					
Unable to brush properly	1.00(1.11)	0.53(0.68)	.000	0.47	+0.52
Avoid eating some food	2.00(1.41)	1.16(0.87)	.000	0.84	+0.73
Interrupted sleep	1.63(1.06)	0.93(0.73)	.000	0.70	+0.78
Psychological disability					
Depressed	1.63(1.47)	1.06(1.08)	.000	0.57	+0.44
Bit embarrassed	1.60(1.35)	0.96(1.03)	.000	0.64	+0.53
Social disability					
Less tolerant of your partner and family	0.96(1.15)	0.46(0.68)	.001	0.50	+0.54
Handicap					
General health worsened	0.73(0.94)	0.46(0.62)	.000	0.27	+0.21
Unable to work to full capacity	0.93(1.04)	0.60(0.67)	.000	0.33	+0.38

7.7 VALIDITY OF THE MEASURE

7.7.1 FACE VALIDITY OF THE MEASURE

Face validity relates to the appropriateness and acceptability of the measure to the target population. In this study an in-depth literature review of all the existing oral health outcome measures developed for adults was conducted to ensure that all items present in questionnaire encompassed in seven domains were relevant to the endodontic treatment. The questionnaire was initially piloted on colleagues and patients to explore and find any questions, confusing, irrelevant, also researcher explored the possibility of any issues important felt by taking contemporary expert opinion from clinicians involved in treatments at primary dental care settings.

7.7.2 CONTENT VALIDITY OF THE MEASURE

Contemporary expert opinions and the in-depth literature review strongly supported the content validity of the questionnaire. For every question/item we encountered a non response rate of < 1%. None of the item was identified weak when the non response rate was distributed across the question items, supporting the view that the instrument is acceptable to patients.

7.7.3 (PAIRED SAMPLE T TEST) AT INDIVIDUAL ITEM LEVELS

There is a significant difference in pre and post treatment levels as in final column of the Table 7.7.3 labelled Sig. (2-tailed) the values of each individual item in the questionnaire is less than .05 which leads to a conclusion that there is a significant difference between pre and post treatment scores. The Wilcoxon test, when conducted also showed the similar results as the values for each individual item in the questionnaire is less than .05, the difference between the two scores is statistically significant.

The ETA squared test was conducted for each item (.70;.76;.23;.38;.61;.32;.27;.38;.64;.47;.46;.34;.44;.43;.65;.79). Cohen J (1988) has described the following in relation to the effect sizes .01=small effect, .06=moderate effect and .14=large effect. Examination of the data presented in Table 7.7.3 suggests we can conclude that there was a large effect, with a substantial difference in scores obtained before and after intervention.

The validity of the measure is statistically significant (p=0.000) when analysed at domain levels.

TABLE 7.7.3: VALIDITY OF THE MEASURE (PAIRED SAMPLES TEST) AT INDIVIDUAL ITEM LEVELS (N=30)

Items	Paired Differences					t	df	Sig. (2-tailed)
	Std. Deviation	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		Mean	Std. Deviation	Std. Error Mean
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper
Trouble pronouncing any words	.30000	.46609	.08510	.12596	.47404	3.525	29	.001
Sense of taste worsened	.30000	.53498	.09767	.10023	.49977	3.071	29	.005
Food catching	1.13333	.62881	.11480	.89853	1.36813	9.872	29	.000
Painful aching in mouth	1.00000	.78784	.14384	.70582	1.29418	6.952	29	.000
Sore jaw	.70000	.87691	.16010	.37256	1.02744	4.372	29	.000
Sensitive teeth	1.10000	.75886	.13855	.81664	1.38336	7.940	29	.000
Toothache	1.26667	.78492	.14331	.97357	1.55976	8.839	29	.000
Unable to brush	.46667	.62881	.11480	.23187	.70147	4.065	29	.000
Avoid eating some food	.83333	.79148	.14450	.53779	1.12888	5.767	29	.000
Interrupted sleep	.70000	.65126	.11890	.45682	.94318	5.887	29	.000
Worried by dental problems	.86667	.62881	.11480	.63187	1.10147	7.549	29	.000
Felt depressed	.56667	.50401	.09202	.37847	.75487	6.158	29	.000
Bit embarrassed	.63333	.55605	.10152	.42570	.84097	6.238	29	.000
Less tolerant of your partner and family	.50000	.68229	.12457	.24523	.75477	4.014	29	.000
General health worsened	.26667	.52083	.09509	.07219	.46115	2.804	29	.009

TABLE 7.7.3.1: VALIDITY OF THE MEASURE (PAIRED SAMPLES TEST) AT INSTRUMENT LEVEL (N=30)

Domains	Mean diff	95% CI	P value
Functional limitation	1.7	(1.3,2.1)	0.000
Physical pain	4.0	(3.3,4.9)	0.000
Psychological discomfort	0.87	(0.63,1.1)	0.000
Physical disability	2.0	(1.4,2.6)	0.000
Psychological disability	1.2	(0.86,1.5)	0.000
Social disability	0.50	(0.24,0.75)	0.000
Handicap	0.60	(0.31,0.88)	0.000

7.8 RELIABILITY OF THE MEASURE

The Cronbach's alpha values of 0.5-0.7 are considered to indicate sufficient reliability for an instrument. In this case the Cronbach's alpha values were above 0.85 which statistically have proven reliability of the measure as evident from Table 7.8.

TABLE 7.8: RELIABILITY OF THE MEASURE (CRONNBACH'S VALUES) (N=30)

Conceptual dimension and items	Pretreatment Corrected Item-Total Correlation	Postreatment Corrected Item-Total Correlation	Pretreatment Cornbach's Alpha If Item Deleted	Posttreatment Cornbach's Alpha If Item Deleted
Functional limitation				
Trouble pronouncing any words	.353	.363	.938	.936
Sense of taste worsened	.360	.375	.937	.936
Food catching	.398	.260	.936	.937
Physical pain				
Painful aching in mouth	.667	.653	.933	.934
Sore jaw	.260	.379	.938	.936
Sensitive teeth	.725	.553	.932	.935
Toothache	.765	.601	.932	.935
Psychological discomfort				
Worried	.626	.688	.934	.935
Physical disability				
Unable to brush properly	.680	.745	.933	.933
Avoid eating some food	.585	.601	.934	.934
Interrupted sleep	.744	.675	.932	.933
Psychological disability				
Depressed	.702	.745	.932	.932
Bit embarrassed	.494	.578	.933	.934
Social disability				
Less tolerant of your partner and family	.676	.646	.933	.934
Handicap				
General health worsened	.650	.523	.934	.935
Unable to work to full capacity	.523	.673	.939	.938

7.9 RELATIONSHIP BETWEEN CHANGES IN THE OHIP- EOM AND THE GLOBAL ORAL HEALTH RATING

All items apart from one (trouble pronouncing any word) were correlated with global oral health rating. Correlation is significant at (P=0.01) as shown in Table 7.9.

TABLE 7.9 CORRELATION BETWEEN OHIP- EOM AND GLOBAL ORAL HEALTH RATING (N=30)

Conceptual dimension and items	Pearson correlation against Global Oral Health rating	P value
Functional limitation		
Trouble pronouncing any words	1.000	0.000
Sense of taste worsened	1.000**	0.000
Food catching	1.000**	0.000
Physical pain		
Painful aching in mouth	1.000**	0.000
Sore jaw	1.000**	0.000
Sensitive teeth	1.000**	0.000
Toothache	1.000**	0.000
Psychological discomfort		
Worried	1.000**	0.000
Physical disability		
Unable to brush properly	1.000**	0.000
Avoid eating some food	1.000**	0.000
Interrupted sleep	1.000**	0.000
Psychological disability		
Depressed	1.000**	0.000
Bit embarrassed	1.000**	0.000
Social disability		
Less tolerant of your partner and family	1.000**	0.000
Handicap		
General health worsened	1.000**	0.000
Unable to work to full capacity	1.000**	0.000

7.10 RELATIONSHIP BETWEEN CHANGES IN THE OHIP- EOM AND GLOBAL TRANSITION JUDGMENT SCORES

Changes in measure were correlated with each other at the individual item level, and were statistically significant but against global transition judgments only three items were correlated as shown in Table 7.10.

At domain level also only three domains 'functional limitation', 'physical disability' and 'psychological disability' showed a correlation with global transition judgement score (Table 7.10.1).

TABLE 7.10: RELATIONSHIP BETWEEN CHANGES IN THE OHIP-EOM AND GLOBAL TRANSITION JUDGMENT SCORES AT INDIVIDUAL ITEM LEVEL (N=30)

Conceptual dimension and items	Pearson correlation	P value	Pearson correlation against Global transition judgment scores	P value
Functional limitation				
Trouble pronouncing any words	0.982**	0.000	0.466**	0.009
Sense of taste worsened	0.948**	0.000	0.206	0.274
Food catching	0.817**	0.000	0.116	0.542
Physical pain				
Painful aching in mouth	0.830**	0.000	0.253	0.177
Sore jaw	0.664**	0.000	0.345	0.062
Sensitive teeth	0.782**	0.000	0.055	0.771
Toothache	0.679**	0.000	0.217	0.250
Psychological discomfort				
Worried	0.863**	0.000	-.024	0.900
Physical disability				
Unable to brush properly	0.863**	0.000	0.000	1.000
Avoid eating some food	0.865**	0.000	0.155	0.413
Interrupted sleep	0.799**	0.000	0.440**	0.015
Psychological disability				
Depressed	0.966**	0.000	0.460**	0.011
Bit embarrassed	0.926**	0.000	0.227	0.228
Social disability				
Less tolerant of your partner and family	0.850**	0.000	0.069	0.716
Handicap				
General health worsened	0.855**	0.000	0.159	0.402
Unable to work to full capacity	0.877**	0.000	0.206	0.275

TABLE 7.10.1: RELATIONSHIP BETWEEN CHANGES IN THE OHIP-EOM AND GLOBAL TRANSITION JUDGEMENT SCORES AT INSTRUMENT LEVEL (N=30)

Conceptual domains	**P value**
Functional limitation	0.05
Physical disability	0.05
Psychological disability	0.05

7.11 WILCOXON SIGNED RANK TEST

The Wilcoxon test concludes that the difference between the two scores is statistically significant ($p<.0005$). Therefore we can conclude that the two scores are significantly different before and after treatment as shown in Table 7.11.

TABLE 7.11: WILCOXON SIGNED RANK TEST (N=30)

Conceptual dimension and item	Z	Asymp. Sig. (2-tailed)
Functional limitation		
Trouble pronouncing any words	-3.000(a)	0.003
Sense of taste worsened	-2.714(a)	0.007
Food catching	-4.660(a)	0.001
Physical pain		
Painful aching in mouth	-4.278(a)	0.000
Sore jaw	-3.384(a)	0.000
Sensitive teeth	-4.456(a)	0.001
Toothache	-4.602(a)	0.000
Psychological discomfort		
Worried	-4.400(a)	0.000
Physical disability		
Unable to brush properly	-3.276(a)	0.000
Avoid eating some food	-3.852(a)	0.000
Interrupted sleep	-4.001(a)	0.000
Psychological disability		
Depressed	-4.123(a)	0.000
Bit embarrassed	-4.146(a)	0.000
Social disability		
Less tolerant of your partner and family	-3.217(a)	0.001
Handicap		
General health worsened	-2.530(a)	0.011
Unable to work to full capacity	-2.887(a)	0.004

7.12 MULTIVARIATE LINEAR REGRESSION ANALYSIS

This multivariate regression analysis in Table 7.12 at item level shows that the measure is responsive to change regardless of gender and age. R^2 Interpret as: .01 ~ small

.06 ~ medium

.14 ~ large

TABLE 7.12: MULTIVARIATE ANALYSIS AT INDIVIDUAL ITEM LEVEL (N=30)

Conceptual dimension & items	F	Sig	R^2
Functional limitation			
Trouble pronouncing any words	.684	.570	.271
Sense of taste worsened	.257	.856	.170
Food catching	.981	.417	.319
Physical pain			
Painful aching in mouth	1.121	.359	.338
Sore jaw	1.143	.350	.341
Sensitive teeth	3.198	.040	.519
Toothache	.405	.750	.211
Psychological discomfort			
Worried	.519	.673	.238
Physical disability			
Unable to brush properly	2.819	.059	.495
Avoid eating some food	.598	.622	.254
Interrupted sleep	.125	.944	.119
Psychological disability			
Depressed	.520	.672	.238
Bit embarrassed	.375	.772	.204
Social disability			
Less tolerant of your partner and family	.684	.570	.271
Handicap			
General health worsened	.170	.915	.139
Unable to work to full capacity	.684	.570	.271

The analysis shows R^2 ranging from (.119-.495) which proves that measure is stable regardless of any external factors.

TABLE 7.12.1: MULTIVARIATE ANALYSIS AT INSTRUMENT LEVEL (N=30)

Domains	95% CI	P value	R^2
Functional limitation	(-0.51,-0.28)	0.000	0.69
Physical pain	(-0.62,-0.42)	0.000	0.82
Psychological discomfort	(-0.52,-0.20)	0.000	0.46
Physical disability	(-0.49,-0.30)	0.000	0.77
Psychological disability	(-0.38,-0.20)	0.000	0.63
Social disability	(-0.64,-0.41)	0.000	0.79
Handicap	(-0.41,0.04)	0.000	0.80

The analysis at domain level shows R^2 ranging from (.46-.82) which also proves that measure is stable regardless of any external factors.

7.13 SUMMARY

In summary, the findings in this chapter suggest that the EOM is sensitive and responsive to the effects of endodontic treatment. The results demonstrated reliability, validity and responsiveness of the newly developed Endodontic outcome measure (OHIP-EOM). These findings have implications for use of this newly developed brief measure as an outcome measure for endodontic treatment.

The next chapter discusses the findings of the study and their implications for action.

CHAPTER 8 DISCUSSION

8.1 INTRODUCTION

This study resulted in the development and evaluation of a short health outcome measure for endodontic treatment that could be used in a clinical setting to evaluate outcomes for clinical interventions. This short form of OHIP-49 has demonstrated reliability and sensitivity to change in the context of primary dental care provided in a dental hospital and may be known as EOM (Endodontic Outcome Measure). This study is a step forward towards providing the empirical evidence that endodontic treatment improves OHQOL.

Although it has been shown to be one of the most comprehensive subjective oral health measures (Slade and Spencer, 1994) the original OHIP-49 is not practical in the clinical setting because of its length (Allen and Locker 2002) it constraints a time burden of at least 15 minutes on respondents as well as many questions are not relevant to specific oral health states. Locker and Allen (2002) have discussed why we may need to shorten a long measure: (1) a measure takes a long time to complete and sore may not be feasible in clinical settings; (2) a long questionnaire can increase the cost of administration and data management; (3) respondent burden may mean that it may not be feasible to sue in some population group, and (4) item non response rate may be higher in long questionnaires and may lead to a substantial loss of data. Although a number of shortened measures have been developed and tested OHIP-14 developed by Slade (1999) has been employed in a number of studies; however, only one study has used 17 items chosen by the researchers that reflected elements that can be related to endodontic disease from OHIP-49 to evaluate the outcomes of endodontic treatment (Dugas N et al., 2002). However, the purpose of the study was to assess the quality of life and satisfaction in relation to endodontic treatment in two populations and the association of these outcomes with treatment provider's level of training (general dentist or an endodontist). In this study we have aimed to develop a short but comprehensive instrument through multicollinearity, factor analysis, regression analysis and an expert-based approach for endodontic treatment by collecting data in a primary dental care setting.

The discussion is divided into following sections:

A. Development of the instrument.
B. Testing of the instrument.

8.2 INSTRUMENT DEVELOPMENT

Juniper et al. (1996) and Guyatt et al. (1985) have discussed this section of the instrument in four stages:-

1. Specifying measurement goals.
2. Item generation.
3. Item reduction.
4. Questionnaire formatting.

Each of these stages will be discussed in turn below:

8.2.1 SPECIFYING MEASUREMENT GOALS

In this stage a researcher has to define exactly what instrument is to measure. In this study the aim of the study was to evaluate outcomes of endodontic treatment in clinical settings. It is important, however, to note that whole study was conducted in primary dental care settings, albeit within a dental hospital. The convenience sampling technique was employed to recruit adult patients presenting for endodontic care in primary dental care settings. This is the best choice of non-probability sampling as a good representation of the overall population is possible in a reasonable time frame. In this sample the entire patients with the condition within the hospital or clinic are included, not just the investigators happen to know about. In this study a strict protocol was followed by definitions of conditions of interest and a straightforward way was used to enrol subjects, explicit effort was made to identify and recruit all persons with conditions of interest.

In the literature there has been a reported need for research in primary dental care settings (Hopkins et al 1996; Burke, 1997), this study has demonstrated that it is feasible to carry

out research in primary dental care setting of a dental hospital amongst patients selected because they required endodontic care. The majority of the patients approached agreed to take part in the study despite the length of the questionnaire in stage II of the study. The retention rate was 95.2% in stage II of the study. In stage III of the study retention rate was 100% one of the possible factors of such a rate was the short questionnaire as it had only 16 items. The successful retention rate may be attributed to a number of possible factor's: Researcher was present to assist patients as well as supporting clinical staff assist in keeping tracks of patient appointments, patients had ample time in waiting rooms before being called in for their appointments as well as were approached by the researcher after their appointments to make sure they completed the post-treatment questionnaires, patients were aware of the fact that teaching hospitals have research activities which help to improve services provided to patients.

The use of oral health quality of life measure can gather helpful information about dental primary care users as well as how oral health affects quality of life. However, a lot of effort is required by researcher and clinical staff to keep track of appointments of patients presenting for care especially if patient's have to be followed for follow up appointments.

8.2.2 ITEM GENERATION

In this study, a detailed review of existing core and expanded oral health quality measure for adults was conducted to generate a list of 58 relevant items based on sound theoretical models as outlined in chapter two the importance of which was stressed by Allen (2003) in a review article. DeVellis (2003) has highlighted that items devised from an invalid model run the risk of being inadequate so instruments based on published theoretical model were thoroughly evaluated to generate items for questionnaire for this study.

Streiner and Norman (1995) have suggested that the team involved in development of a new measure needs to thoroughly review the literature before they make plans to develop a new instrument. The patience and effort required to develop a new method of measurement are great, and much time can be saved if a suitable instrument already exists. Despite a dearth of QoL measures have been developed and reported on in the literature, no discipline-specific measure in the field of Endodontic has been developed to date apart

from one developed by Dugas et al. (2002) in which items from OHIP-49 were selected to reflect those elements that can be related to endodontic disease. In our study we have attempted to review all the existing core oral health–related quality-of-life (OHRQoL) measures to generate items for stage II of the study. The approach to generate items from literature review has been outlined by Krishner and Guyatt (1985).

8.2.3 ITEM REDUCTION

Item reduction in this study was undertaken by both regression analysis and expert based approach reducing the items from 58 to 16. Variation exists in methodology with regard to item reduction. Item reduction can be carried out by the judgment (Juniper et al., 1997) or by statistical methods, such as use of the Rasch theory or factor analysis (Guyatt et al., 1997). In an article by Juniper et al. (1997) a comparison was made between item reduction by the judgment and item reduction by factor analysis. The authors found that two very different instruments were derived from the same item pool when using the different approaches to item reduction (Juniper et al,. 1997); however they suggest that factor analysis is the older and more conventional method for selecting items for a questionnaire. This method was used to develop asthma specific health related quality of life instrument (Marks et al,. 1992). Guyatt et al. (1992) have already discussed that if the purpose is to use the instrument in a clinical trial to evaluate change over time, the instrument's responsiveness and longitudinal correlations with independent measures will be the key properties that must be tested. This was done in this study as it was correlated against global oral health rating and global transition judgement. Wong et al. (2007) have used a similar approach to develop a short form of OHIP for dental aesthetics both by the regression analysis approach (14 items measure) and experts based approach (14 items measure) and have reported a strong correlation with self oral health rating. Slade (1997) used the similar approach to develop OHIP-14 in which factor analysis and regression analysis was used to develop a subset of questionnaire from OHIP-49 and reported good reliability and validity of the measure. In our study GOHAI 12 items have to be discarded after statistical analysis as all items showed extreme multicollinearity (i.e. variables that are very highly correlated) (Appendix A). There is greater evidence for the robustness of the full OHIP, as an instrument (Locker, 2002). GOHAI was discarded rather than OHIP. Locker (1998) has discussed that the major advantage of the OHIP measure is that the

statements were derived from a representative patient group, and were not conceived by dental research workers. “This increases the possibility of the measure "tapping into" social consequences of oral disorders considered important by patients, and is considered to be the most sophisticated measure of oral health” (Locker, 1998). Spearman correlation was used; as it gives as much information as the Pearson correlation coefficient and is of wider validity, as discussed by Altman (1991). A systematic review of the literature conducted on the use and performance of OHIP concluded that the instrument is sensitive enough to capture changes in the impact of oral conditions (Miotto et al., 2001). However, it has been further suggested there is little scientific evidence to recommend the use of the OHIP instrument in isolation, be it in planning or assessing oral health services. Its use should be considered complementary to traditional objective indicators ((Miotto et al., 2001). Locker et al. (2001) have also suggested that differences in item content may mean that the GOHAI is better at detecting impacts in the form of dysfunction and pain, while the OHIP is better at detecting psychosocial impacts. The GOHAI measures patient-reported oral function issues and assesses psychosocial impact as reported by (Atchison and Dolan, 1990) but the strength of the OHIP is that it is that it is derived from Locker’s conceptual model of oral health and is the most commonly used socio-dental indicator (Locker, 2004). However, Mc Grath et al., (1999) have suggested that it can be considered to as a generic oral health status measure rather than a condition-specific measure. Literature review suggests that different short form of the OHIP can be developed to accommodate a specific oral health state (Wong et al., 2007; Allen and Locker, 2002).

Factor analysis was conducted on the 46 items from OHIP-49, supported by an expert based approach and followed by regression analysis. This approach in developing an endodontic outcome measure was very different to that of Dugas et al., (2002) study in which only expert-based approach was used that led to differences in the resultant short-form instruments. First OHIP-EOM is a shorter measure by one item, with 16 instead of 17 items; and second, only six of the items are the same as Dugas et al. (2002): ‘trouble pronouncing any words’, ‘sense of taste worsened’, ‘painful aching’, ‘interrupted sleep’, ‘been embarrassed’ and ‘unable to work to full capacity’ This research lends support to Juniper’s (1997) premise that the approach to item reduction influences the form of the resulting instrument.

In this study factor loading was kept at >0.40 which was the same value used by Wong et al (2007) to develop OHIP-aesthetics. Factor loadings >. 30 are considered to meet the minimal level; loadings of >. 40 are considered most important; and if the loadings are >. 50 or greater, they are considered practically significant (Joseph et al., 2009).

8.3 TESTING OF THE INSTRUMENT

8.3.1 INTRODUCTION

First the study has shown that it is possible to produce a relatively short and simple list of items (John et al., 2004) that are relevant to functional and psychosocial domains and scores can be produced that can be statistically analysed. Second test-retest (paired sample t test) has produced highly consistent results, suggesting instrument is stable. Third multivariate analysis of stage III has shown that the measure is responsive to change regardless of gender and age.

There was a significant decrease in the newly developed outcome measure scores, indicative of a reduction in the burden of oral disease, an indication of an enhancement in oral health quality of life. This measurement represents the patient's views about their response to therapy as well as demonstrated the sensitivity of this patient centred measure for the management of oral disease; therefore this can be used as a potential outcome measure in evaluating the effectiveness of relevant oral health care.

In developing condition specific measures of HRQL Guyatt et al. (1989) have stated that certain criteria need to be fulfilled:

1. Summary scores should be amenable to statistical analysis.
2. Repeated administration in stable patients must yield similar results.
3. When even a small clinical important change has occurred, the questionnaire should reflect it.
4. The questionnaire should be valid
5. The questionnaire should be relatively short and simple.

The study shows that all criteria were fully investigated when the instrument was administered in stage III of the study at the beginning and the end of the endodontic treatment.

8.3.2 RESPONSE AND RETENTION RATES

Non-response and dropout attrition could be a major problem in most longitudinal studies. Response rates can be discussed in terms of unit response or item response (Lesaffre et al., 2009). The attrition rate of the stage II of the study was 96%, and had a very low drop-out rate of less than 4%. Obtaining high response rates usually lowers the probability of serious non-response bias (Locker D, 2000). The response rate of stage III was 53%. This compares favourably with a study conducted by Wong et al (2007) to develop OHIP-aesthetics in which response rate was 57%. Heydecke et al (2004) also have reported 48.8% response rate to assess OHRQOL of edentulous patients with conventional complete dentures.

8.3.3 SCORING METHOD

In this newly developed outcome measure the frequency of each impact was reported on a five point Likert scale (never; hardly ever; occasionally; fairly often and very often) with 0 being never to 4 being very often. Prevalence and severity were constructed and used as outcome variables. Prevalence described the percentage reporting one or more item (occasionally, fairly often; and very often). Severity described the sum of ordinal response which takes into accounts the impacts also experienced (occasionally, fairly often and very often). Item wise analysis of the new measure is described in Table 7.3 in chapter 7 stage III of the study.

In this study the items within the instrument was not weighted. In some studies, 'weighing' of the OHIP items was performed as to obtain a reflection of the relative importance of each question in the subject (Cushing et al., 1986; John et al., 2002). In the present study, full question weights was not determined or used, because they did not result in improvements of measurement properties in the recent study by John et al. (2002). The

technique used in measuring scores in new outcome measure was, recommended by Slade (1997), consists of counting ‘occasionally’; 'fairly often' and 'very often' responses only, implicating that these questions would be more important for the patient than questions scoring 'never', or 'hardly ever' to compute scores by counting the numbers of items reported occasionally, fairly often and very often, and therefore they rely on the threshold of reported impact. However, Slade (1997) further discusses that this measure is simple to compute and interpret it fails to take advantage of the full range of responses for each question as this threshold can probably contribute to false positive reports but when he used the standardized scores which are the preferred method for examining associations between explanatory factors and reported impacts same conclusion was reached. When applied to the present data, the Pearson correlation between the sum scores of all responses (i.e., the method used in this study) and the count summary scores was in between (0.6-0.9) (P = 0.00). This corroborates the recommendation of John et al. (2002) not to weigh OHIP items for most purposes.

8.3.4 RESPONSIVENESS

The instrument demonstrated responsiveness both at the item and instrument level as reported in section 7.5 and 7.6 (Chapter 7). Our principle aim of this study was to assess responsiveness, or sensitivity to change, of the EOM. This is a key property of a health outcome measure, as assessment of the nature and magnitude of change following clinical interventions is a concern of patients, health providers and fund providers alike. If the instrument is to be used in an evaluative context, then it must be responsive to small but important changes in health. Assessment includes computing an effect size statistic, the distance between before and after scores. But no consensus exists on the statistical measure (Streiner and Norman, 2008).

The responsiveness of measure was assessed by comparing scores before and after treatment and by effect size. Responsiveness was tested by analysing data at pre and post treatment level. The sample size of 30 was in accordance with a number of studies including work by Guyatt el al. (1987) in which sample of 28 patients was used to validate asthma quality of life questionnaire. There was observed changes in scores overall and among several of the domain scores, namely functional limitation, physical pain and the

psychological discomfort. The greatest mean change in scores was observed in the physical pain domain presumably that several items in this domain related directly to the pain and soreness associated with endodontic treatment. For example within physical pain domain the highest score was observed in item “toothache”.

Cohen’s standardised effect sizes is the most popular approach when interpreting the magnitude of change based on effect size. In this approach the mean change is divided by the standard deviation to serve as an ‘effect size index’ (Cohen et al., 1986). Standardised effects of less than 0.2 can be categorized as a having a ‘minimal effect’; in between 0.2 to 0.49 are regarded as having a ‘small’ effect; effect sizes of 0.5-0.8 as having a ‘moderate effect’ and those above 0.8 as having a ‘large effect’. Thus, the magnitude of change in this measure 0.9 in response to endodontic treatment among this study group could be regarded as large. This is similar to the results of Slade et al. (1996) in a study of older adults in North Carolina. According to Bland and Altman (1997), Cronbach’s alpha of 0.70 to 0.80 is satisfactory for comparisons between groups, while an alpha of 0.90 is needed for clinical use. Streiner and Noramn (2008) have discussed that assessment includes computing an effect size statistic, the distance between before and after scores. But no consensus exists on the statistical measure.

The values of internal consistency obtained in this thesis indicate exemplary internal consistency according to McDowell and Newell (1996). As among the domains functional limitation, physical pain and psychological discomfort a high magnitude of change was observed. These results were higher to those previously reported by Slade & Spencer (1994) who obtained Cronbach's alpha coefficients ranging between 0.70 and 0.83 for six subscales and similar to 0.37 obtained in the deficit subscale. The present study also showed higher results than those previously reported by Slade and Spencer (1994) in a study of older adults in two Australian cities that were between 0.42 and 0.77 for six subscales, and higher than 0.08 for social disability. These findings are much similar to those reported by Locker and Slade (1993) in a study of older people in Ontario who found values ranging between 0.80 and 0.90 for all components. However, they are lower than 0.96 Cronbach's alpha coefficient obtained by Slade et al. (1996) and 0.88 obtained by Slade (1997). Silva (2001) described an internal consistency measured using Cronbach's alpha coefficient ranging between 0.61 for psychological disability and 0.77 for psychological discomfort assessed using the simple intraclass correlation coefficient. The

obtained values ranged from 0.44 for psychological disability to 0.62 for psychological discomfort.

In general the higher the proportion of "high prevalence items" (i.e items with high frequency) the better the measure is likely to be detecting change. This study has reported a number of high prevalence items in functional, physical and psycho social domains. Similar findings have been reported by (Slade et al., 1996), identified individuals with dental caries showing the highest scores that were associated with the greatest impact.

Although the sample size was small for the responsiveness testing it is comparable to previous studies conducted by Cunningham et al. (2002) in the development of a condition-specific quality of life measure for patients with dentofacial deformity. II: validity and responsiveness testing in which he recruited 30 patients. The sample size in this study was in accordance with a number of previous studies including work by Guyatt et al. (1987) who used 13 patients in one study and 28 in another.

Results reported significant differences in EOM scores after treatment support the claim that the instrument has acceptable psychometric properties.

8.3.5 RELIABILITY

The reliability scores for this instrument for each item were above 0.90 cronbach's alpha value. The outcome measure internal consistency was first evaluated by analysing the matrix of inter-item correlations which found a positive correlation between all items. The standardised Cronbach's alpha value derived from the correlation matrix was above 0.85 for all items. Alpha coefficients above 0.8 are exemplary, in the range between 0.70 and 0.79 extensive and coefficients in the range between 0.60 and 0.69 indicate moderate internal consistency.

Reliability of any measurement or scale score is essential, and this thesis presents reliability data for the instruments. Excellent reliability for all domains was found, for both internal consistency and test-retest reliability. This agrees with the original Slade and Spencer study (1994), which assessed reliability in the same manner demonstrating good

internal consistency in six of the seven subscales in the original version. The Handicap subscale had a lower Cronbach's alpha than the others. These findings are similar to those reported by Locker & Slade (1993) who found values ranging between 0.80 and 0.90 for all components. Our excellent test-retest reliability is also in line with studies of other OHIP versions. (Allen and Locker 1997; Rener-Sitar et al., 2008; Slade and Spencer 1994; Slade et al., 1996).

8.3.6 VALIDITY

To ensure the meaningfulness of the newly developed instrument different types of validity were examined: face validity, content validity, and subtypes of construct validity, each of which will be addressed in turn below.

8.3.6.1 FACE VALIDITY

The motivation of the respondents to complete questionnaires for all stages of the study and no missing or misunderstanding items in the pilot study confirmed the face validity of the questionnaire.

The instrument face validity was confirmed as in stage II despite being a lengthy instrument 95% of the respondents (N=101) who agreed to take part in the study completed the pre-treatment, post-treatment and follow-up questionnaires. 100% of the respondents (N=30) who agreed to take part in stage III of the measure the final instrument stage completed the both questionnaires pre and post-treatment. Robinson et al. (2003) has already confirmed that OHIP-14 has superior face validity and is more suitable for questionnaire based approach and for comparing groups as compared to OIDP. The newly developed measure fits onto one side of paper with all 16 items and the possible responses are arranged in matrix as compared to OHIP-14 discussed by Robinson et al. (2003). Face validity was confirmed in the pilot study with no missing or misunderstanding items. The simple format of the self-administered questionnaire with a frequency Likert-type scale of self-reported oral impacts was considered sufficient by the researchers to verify its face validity.

8.3.6.2 CONTENT VALIDITY

The difference between mean scores before and after treatment demonstrated satisfactory content validity of the instrument. The content validity is considered satisfactory of the new measure as it enquires into a broad spectrum of physical, psychological and social dimensions potentially affected by oral conditions and because these dimensions emerge from a sound theoretical base model of oral health developed by Locker (1988). The currently developed measure focuses on impacts of the same problems at several stages of the model.

8.3.6.3 CONVERGENT VALIDITY

A global self-rating of oral health has also been used to measure study participants' oral health status. Respondents are asked to rate their oral health from poor to excellent on a 5-point Likert scale. Matthias et al. (1995) used this approach in Los Angeles whereas Dolan et al. (1998) used this approach to study change in oral health among dentate elderly adults in Santa Monica, California. The global rating was also used as the criterion to validate other composite, and more complex, measures of oral health (Kressin et al., 1997; Cushing et al., 1986, Locker 1994; Matthias et al., 1995). Rowan (1994), in a review of the assessment of global rating in general health with complex system-specific measures of general health status, pointed out that global measures provide information that, at the very least, is consistent with that derived from the more complex methods of assessment. Nevertheless, the global rating of health status obscures information at an individual system (domain) level. It suffers from a limitation referred to as 'end' effect; this is the tendency of health measures to identify only people at the extremes of health. Compared to comprehensive health status instruments, the global rating is stated to have less explanatory power (Dolan et al., 1991).

A Global measure of oral health was included in this study in stage II and stage III questionnaires, because they are simple to use and have been commonly used measures against which others may be compared (Osoba, 1998). Global oral health rating showed a tendency to detect a treatment effect in this study also it showed a strong relationship with

the newly developed outcome measure. The global rating correlated highly with the change score of the newly developed outcome measure. Quality of life indicators are designed to measure health from a holistic conception which is increasingly recognized as including psychological and sociological aspects that only can be expressed by subjective feelings (Sheiham et al., 2001; Robinson et al., 2003; Allen et al., 1999). The results confirmed this since the highest correlation between self-rated oral health rating and the seven subscales was found ($P<0.001$). Similar results have been reported by Wong et al. (2007) for OHIP-aesthetics ($P<0.001$). Locker et al., (2001) in a study to measure the oral health-related quality of life of the compromised elderly also showed significant associations with self-rated oral health and satisfaction with oral health status. However, Benyamini et al., (2004) have reported that oral health satisfaction is more strongly related to comprehensive measures of OHRQoL than the traditional single global items of oral health perception.

It was interesting to note from the results that the global transition judgement was not highly correlated with the newly developed outcome measure it only showed correlation with three items (depressed, avoid eating some foods and trouble pronouncing any words).The global transition judgement is single item measure and easier to collect and analyse but Ware et al., (1981) have discussed that they may not measure the complex concept of OHQOL and are less precise. Norman et al., (1997) have also argued that global transition judgment statements are not valid as they are more likely to be related to the subjects rating of their current health rather than their change in oral health status. Locker et al., (2004) have used global transition judgement as a gold standard to measure responsiveness of OHIP-14 on an elderly sample but the magnitude of change was modest, Locker has further discussed that there is a need for further research in terms of justifying global transition judgement as a gold standard to assess the responsiveness of the measure. To date there is no consensus in research to measure responsiveness. So the different responsiveness of the newly developed measure and global transition judgement scores is not surprising. However, sixty percent (n=18) showed their quality of life improvement after completion of endodontic treatment. Locker et al., (2003) have also reported that 60.2% of subjects reported improved oral health when used to evaluate a dental care program for the elderly. None of the respondents reported that their oral health was a lot worse after completion of the endodontic treatment. This is in line with Locker et al.,

(2003) study in which similar results were reported when used to evaluate a dental care programme for the elderly.

We also found no considerable differences in EOM scores when socio-demographic variables such as age and gender were taken into account. This finding is in line with findings reported by Cohen et al (2011) that a great number of studies did not find a significant association between gender and OHRQoL impacts on bivariate analyses. Also have further reported association between age and the subjective impact on oral health is still unclear.

8.4 Study Limitations

There are a number of limitations to this study, each of which will be addressed in turn. First the ethics committee did not allowed recruiting patients for study when they were in acute phase given, the relatively short lived impact of endodontic disease and quality of life would have been better to assess at time when the patient actually experiences that impact. Second the study did not collect data on general health/social/dental/ other issues patient's quality of life may have been influenced by these factors while this study was conducted. Third, it did not collect data on the location of the tooth may have been an important factor in effecting quality of life. Fourth the sample size was relatively small in validation of the study however; results demonstrated good reliability, validity and responsiveness of the measure. Fifth the outcomes were only short-term outcomes and to be certain, patients should be followed up for at least four years along with clinical and radiological outcomes. This is an area that needs to be considered in further research. Sixth the study was conducted in dental hospital however, it is important to recognise that the findings suggest that dental students were achieving measurable patient outcomes.

Our study preliminary findings are based on convenience sampling. Consequently, the findings reported here may not be generalizable to patients in different clinical settings This means that the study needs to be repeated on different samples recruited from different locations in order to confirm the psychometric properties of the measure. The problem of sample size in Stage III was solved by using confidence intervals. Most of the statistical significant associations observed showed a substantial magnitude.

CHAPTER 9 CONCLUSIONS AND RECOMMENDATIONS

9.1 CONCLUSIONS

1. This study is the first attempt in the UK to assess a population's perception of the impact of endodontic disease on quality of life in a primary dental care setting and how it can be improved after endodontic treatment. The newly developed endodontic outcome measure (EOM) appears to have good reliability and acceptable validity. It has been shown to capture oral disorders associated with endodontic treatment.

2. The EOM has shown sensitivity to changes and was more sensitive to measure changes in patients after completion of endodontic treatment.

3. The EOM appears to provide a standardized approach to assess the magnitude of the effect of the endodontic treatment on quality of life of patients with minimal burden for the patients.

4. The EOM was found acceptable to respondents which as demonstrated by the high completion rate of the questionnaire.

5. The EOM is very brief which makes it suitable to be used along with other instruments, for example with generic instruments or any traditional clinical outcome measure.

6. The EOM can be used to analyse the difference in the magnitude of improvement in quality of life by administrating it to patients under the care of specialist clinics and general dental practitioners.

9.2 RECOMMENDATIONS

1. Further research is needed to assess sensitivity to change the responsiveness of the newly developed EOM from clinical trials/clinicians need to be involved to collect data and interpret it.

2. There is a need for to explore how patients perceive change scores of the newly developed EOM in relation to their global transition of oral health status change as it would provide valuable insight into how patients perceive endodontic treatment.

3. Further research should be undertaken to incorporate items that should reflect the positive effects that endodontic treatment can have on quality of life, this can be addressed by using a qualitative approach by asking open-ended questions, thereby allowing the respondents to mention how their quality of life has been affected by their oral health problems.

4. This longitudinal study is a step towards providing the empirical evidence needed to validate the assumption that endodontic treatment improves OHQOL. Further testing is recommended in a range of settings, with longer-term follow-up along with guidelines recommended in quality guidelines for endodontic treatment by the European Society of Endodontology to assess the outcome of endodontic treatment.

5. The EOM is likely to be of clinical relevance in situations such as clinical trials (comparing the effects of treatments) and in quality assurance.

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